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Parenting Acceptance and Commitment Therapy: A randomised controlled trial of an innovative online course for families of children with Cerebral Palsy

Koa Whittingham[1,2], Jeanie Sheffield[2], & Roslyn N. Boyd[1]

[1]Queensland Cerebral Palsy and Rehabilitation Research Centre, School of Medicine, The University of Queensland, Brisbane, Australia;
[2] School of Psychology, The University of Queensland, Brisbane, Australia.

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Declaration of Interest:
None

Address for Correspondence:
Dr Koa Whittingham Queensland Cerebral Palsy and Rehabilitation Research Centre, The University of Queensland
Level 6, Centre for Children's Health Research
62 Graham Street South Brisbane 4101
Email: koawhittingham@uq.edu.au

Abstract

Introduction Cerebral Palsy (CP) impacts upon the entire family in a manner that is long-term, complex and multifactorial. In addition, the quality of the parent-child relationship impacts on many and varied child outcomes, making the provision of easily accessible and evidence-based support to parents of children with CP a priority. This paper reports the protocol of a randomised controlled trial of an innovative and translatable online intervention, Parenting Acceptance and Commitment Therapy (PACT), for families of children with CP. We predict that participating in the PACT program will be associated with improvements in the parent-child relationship, in child functioning, and in adjustment and quality of life for both parent and child.

Methods and analysis We aim to recruit 66 parents of children (2-10 years old) diagnosed with CP to this study. Families will be randomly assigned to two groups: waitlist control and PACT. PACT is a parenting intervention grounded in Acceptance and Commitment Therapy (ACT) and developed into an online course 'PARENT101 Parenting with Purpose' using the edX platform. All participants will be offered PACT before completion of the study. Assessments will take place at baseline, following completion of PACT and at six-month follow up (retention). Analysis will follow standard methods for randomised controlled trials using general linear models.

Ethics and dissemination Ethics approvals have been obtained through the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/15/QRCH/115) and The University of Queensland (2015001743). If efficacy is demonstrated, then the PARENT101 course has the potential to be disseminated widely in an accessible manner and at minimal cost. Further, the PACT framework may provide a blueprint for similar online courses with parents in a full range of contexts.

Registration details This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616000351415).

Keywords: cerebral palsy; online intervention; acceptance and commitment therapy; parenting

Strengths and limitations of this study

Strengths:

- This is a randomised controlled trial using CONSORT methodology
- Assessment includes a parent-child observation coded by blinded coders
- The use of online technology allows for greater flexibility in access and delivery of PARENT101
- PARENT101 course has the potential to be disseminated widely in an accessible manner at minimal cost

Weaknesses:

- The control condition is a wait-list control and will have access to PARENT101 after the completion of post-course assessments for ethical reasons
- Participants cannot be blinded to condition

Cerebral Palsy (CP) Is Not Just a Physical Disability

Motor impairments are the clinical hallmark of CP, however, other impairments are common (Novak, Hines, Goldsmith, & Barclay, 2012). Further, the optimal development of children with CP — psychological, social, emotional and cognitive development — is at risk. One in four children with CP have a behavioural disorder (Novak et al., 2012) compared to one in 10 typically developing children (Costello, Egger, & Angold, 2005). Seven in 10 preschool children with CP show significant delay in social milestones relative to community norms with continued social difficulties at school age (Gehrmann, Coleman, Wier, Ware, & Boyd, 2014; Parkes, White-Koning, McCullough, & Colver, 2009; Whittingham, Fahey, Rawicki, & Boyd, 2010). One in five preschool children with CP show a significant delay in self-care skills (Gehrmann et al., 2014). In the long-term, focussing on adults with CP without intellectual impairment, one in five have not completed high school, four in ten are not living independently, one in two are not competitively employed, and two in three are not in a long-term relationship (Frisch & Msall, 2013). Families want support and solutions, however, families receive little support in optimising their children's psychological, social, emotional and cognitive development or in optimising child quality of life. Increases in parental responsiveness are a key factor in predicting child developmental benefits of early intervention (Mahoney, Boyce, Fewell, Spiker, & Wheeden, 1998), suggesting that parents themselves are pivotal to optimising child development.

Impact of CP on the Whole Family

CP impacts upon the entire family in a manner that is long-term, complex and multifactorial. The birth of a child with CP may precipitate complex care responsibilities, financial hardship, limits to occupational attainments, relationship distress, grief, and social isolation, all of which have further flow-on effects for parent, child and family (Bourke-Taylor, Howie, & Law, 2011). In particular, mothers of children with CP experience greater

parental stress than mothers of typically developing children (Rentinck, Ketelaar, Jongmans, & Gorter, 2007). They are four times more likely to have elevated anxiety symptoms and five times more likely to have moderate depressive symptoms (Barlow, Cullen-Powell, & Cheshire, 2006; Lach et al., 2009). In a cross-sectional study of 818 families of children (8-12 years) with CP living across Europe, parents were five times more likely to be experiencing very high stress levels than the general population. Interestingly, the magnitude of parenting stress was not associated with severity of motor impairment of the child (Parkes, Caravale, Marcelli, Franco, & Colver, 2011), rather parenting stress was associated with child behavioural and emotional problems (Abbeduto et al., 2004; Ketelaar, Volman, Gorter, & Vermeer, 2008; Parkes, McCullough, Madden, & McCahey, 2011; Plant & Sanders, 2007). Parents commonly experience an ongoing grieving process, with grief intensifying during transitions and major child and family life events (Whittingham, Wee, Sanders, & Boyd, 2013). Parents of children with CP parent in an emotional context that may include significant stress, ongoing grief, a loss of typical parenting rewards (e.g., seeing your child walk for the first time), anxiety about the future and a lack of understanding from the broader community.

The developmental abilities of children impact upon the quality of parental caregiving that the child is able to elicit within day to day interactions (Howe, 2006). Children with neurodevelopmental disabilities, who most benefit from optimal parental support, are unable to effectively elicit optimal parental support. Parents of children with CP need to be pro-active, skilled and conscious in their moment by moment parenting choices to provide their children with optimal developmental support. Parenting a child with CP, and optimising their development, involves forward thinking, scaffolding abilities, a commitment to supervision, patience, compassion, behavioural management skills, and effort above and beyond the

optimal parenting of typically developing children. Further, all of that requires a strong and loving emotional bond and parental psychological resilience.

Parental Responsiveness Fuels Development

The quality of the parent-child relationship is important for all children, regardless of individual characteristics, and impacts greatly upon diverse child outcomes, including developmental, emotional, cognitive, behavioural, relational, educational, and quality of life outcomes (Aran, Shalev, Biran, & Gross-Tsur, 2007; Gottman, Katz, & Hoover, 1997; Landry, Smith, & Swank, 2006; Patterson, 1982). A meta-analysis demonstrated that parent-child relationships with high parental responsiveness — prompt, child-directed, contingent and appropriate parenting — are associated with improved cognitive, emotional, behavioural and social outcomes (Eshel, Daelmans, Cabral de Mello, & Martines, 2006). Children who have experienced a warm and emotionally available parent-child bond are more likely to be socially competent and emotionally well-adjusted, establishing stable relationships in later life (Sroufe, 2005). Crucially, language, cognitive reasoning and pre-academic skills are learnt through the day to day interactions of the parent-child relationship. In a longitudinal observational study with 42 families, the quality of everyday parent-child interactions in the first three years of life was found to predict 61% of the variance in rates of vocabulary growth and use, as well as 59% of the variance in a child's Standford Binet IQ score at age three (Hart & Risley, 1995). During everyday relationship-driven encounters, parents provide hour after hour of environmental enrichment: rich, quality experience in verbal skills, cognitive reasoning and playful exploration. Parental responsiveness can be conceptualised as nature's dose-control system for environmental enrichment (Morgan, Novak, & Badawi, 2013), enabling the child to obtain 'just right' stimulation for learning and development organically in day to day life via parent-child interaction and the flow-on effects of such interaction. Nowhere is this more important than in the parent-child relationships of children

with developmental delays or disabilities. These relationships may be built and enhanced through the targeted assistance of various psychological approaches.

Acceptance and Commitment Therapy (ACT): a Promising Approach

Acceptance and Commitment Therapy (ACT, said as the word 'act') is now an accepted part of the broad cognitive behavioural therapy approach (CBT). ACT incorporates: mindfulness or deliberate nonjudgmental attention to moment to moment experience, experiential acceptance or ongoing nonjudgmental contact with psychological events such as difficult emotions, cognitions and memories, and vital living or engagement in meaningful, values-driven activities (Hayes, 2004). The goal of ACT is to increase psychological flexibility: the ability to persist or change one's behaviour, with full awareness of the situational context and one's own present-moment experience, in the service of chosen values. ACT, and related psychological therapies, have a growing evidence base for a diverse range of issues, e.g., occupational stress, depression, anxiety and smoking cessation (Baer, 2003; Grossman, Niemann, Schmidt, & Walach, 2004; Ost, 2008; Ruiz, 2012). Meta-analyses, examining the efficacy of ACT and related psychological therapies with varying dosages (30.0 ± 29.8 hours in Ost, 2008), targeting a variety of issues, have identified moderate effect sizes ranging from 0.5 to 0.75 (Baer, 2003; Grossman et al., 2004; Ost, 2008; Ruiz, 2012). Psychological flexibility, the clinical target of ACT, predicts levels of parental psychological symptoms, experienced parenting burden and symptoms of grief in parents of children with CP (Whittingham, Wee, et al., 2013), as well as parental psychological symptoms, maternal bonding and responsiveness in mothers of infants born preterm (Evans, Whittingham, & Boyd, 2012).

Face to Face Parenting Intervention Incorporating ACT is Beneficial

A parenting intervention incorporating ACT was shown to be efficacious within a three-group RCT (Whittingham, Sanders, McKinlay, & Boyd, 2014; Whittingham, Sanders,

McKinlay, & Boyd, in press; Whittingham, Sanders, McKinlay, & Boyd, 2013). Sixty-seven parents of children (mean age 5.3) with CP participated in the trial. Parents were randomly assigned to: waitlist control, the parenting intervention Stepping Stones Triple P or to a combined Stepping Stones Triple P and ACT group. Families receiving Stepping Stones Triple P alone, compared to wait-list, showed improvements in child behaviour and emotional symptoms. Families receiving the combined Stepping Stones Triple P and ACT intervention, compared to wait-list control, showed improvements in child behaviour, child hyperactivity, child functional mobility performance, child quality of life, parenting style and parental adjustment. During the RCT, face to face delivery was identified as a barrier to effective translation requiring an innovative solution to capitalise on the potential benefits from the ACT-based approach.

Online Therapy Is Effective and Translatable

A meta-analysis of web-based psychological therapy indicates that web-based delivery is effective with an average effect size across intervention types and measures of 0.53 consistent with a medium effect and with greater effect sizes of 0.83 for cognitive behavioural interventions (Barak, Hen, Boniel-Nissim, & Shapira, 2008). Further, 14 RCTs were identified that directly compared web-based psychological therapy with traditional face to face psychological therapy and no significant differences between the two treatment modalities could be found. Online delivery modalities may be an ideal vehicle for low-cost and sustainable knowledge translation directly to parents in all situations, but specifically those families with children with disabilities who may require extra time and assistance therefore reducing the capacity to access traditional forms of support.

If found effective, PACT could be easily and rapidly disseminated population wide. Potentially, families of children with CP, in different countries could access immediate evidence-based psychological support, from first receiving diagnosis onwards, to promote

parent and child flourishing and to harness existing strengths within the parent-child relationship to foster long-term developmental gains for the child. PACT is flexible, and family-centred, leveraging the understanding, skills and the day to day interactions that already exist within the family system for the benefit of both child and family and placing the parents as the central experts in their own child's behaviour.

Aim

Our aim is to demonstrate the efficacy of an innovative, translatable-by-design online parenting support package: Parenting Acceptance and Commitment Therapy (PACT, said as the word 'PACT') for families of young children (2 to 10 years of age) with CP. PACT will be delivered in the form of an online course for parents: PARENT101: Parenting with Purpose.

Hypotheses

We predict that participating in the PACT course, PARENT101: Parenting with Purpose, will be associated with improvements in the parent-child relationship and in both parent and child adjustment and quality of life. Following baseline assessment, outcomes will be assessed post-intervention after the final review session and at 6 months post-intervention (retention of treatment effects).

Methods and Analysis

Design

The study is a randomised controlled trial following CONSORT (Consolidated Standards of Reporting Trials) guidelines. Parents of children with CP will be randomly allocated to one of two groups:

(1) Online Parenting Acceptance and Commitment Therapy (PACT) in the form of the online course: PARENT101: Parenting with Purpose

(2) Wait-list control

Follow up will occur at six months post intervention (retention). The wait-list condition will be offered the intervention after completion of the review assessment.

Recruitment

We aim to recruit 66 parents of children (2 to 10 years old) diagnosed with CP. Families of children with CP will be recruited through the Queensland Cerebral Palsy and Rehabilitation Research Centre, hospitals around Australia, the Australian Cerebral Palsy Register and word of mouth. As PACT uses online delivery, there are no impediments to participants being recruited from across Australia including in regional areas, making this project highly feasible.

Exclusion criteria: as PACT uses integrated web-based delivery, parents are required to have: (1) reliable internet access at home (e.g., ADSL) and be committed to maintaining internet access for the duration of the study; (2) a mobile phone for receiving text messages that they are asked to check regularly throughout the study; (3) an email address for receiving emails that they are asked to check several times a week throughout the study; and (4) access to Skype.

Sample size. To have sufficient power to detect an effect size of 0.40 (power 0.8) a total sample size of 52 is required. If a conservative retention rate of 80% is assumed this leads to a total of 66 families to be recruited.

The PACT Intervention

PACT includes ACT techniques already established in an RCT as effective with families of children with CP, including mindfulness, experiential acceptance and cognitive defusion (Whittingham et al., 2014; Whittingham et al., in press; Whittingham, Sanders, et al., 2013). It includes some techniques from the established parenting literature but focuses on strategies to enhance the parent-child relationship and promote parental emotional

responsiveness. An online course was created using the edX platform, an open source course management system created by founding partners Harvard and MIT (www.edx.org/). The edX platform is used to host Massive Open Online Courses (MOOCs) and allows for the online delivery of a variety of educational courses that can be accessed from anywhere that has internet availability.

Within the edX framework, the PACT program has been developed to give it the look and accessibility of a course and has been named PARENT101: Parenting with Purpose. PARENT101 incorporates: virtual written text, video presentations, screen-based interactive activities, journal activities, reflections, guided experiential and mindfulness exercises and participation in a moderated discussion board. In addition, research participants will be offered Skype sessions with a therapist as well as reminder text messages and emails. PARENT101 is presented as three modules plus a review session 4 weeks after the final module. Modules are scheduled to be completed each fortnight, with a four-week break after that to allow for practise of the materials from the course. Overall the course lasts for 10 weeks (6 weeks for modules plus review 4 weeks later) in total, with parents able to move through each module's content with some flexibility. Access to PARENT101 will be restricted to study participants until efficacy is established.

Study Procedure

After obtaining ethical approval, a recruitment strategy was developed to maximise opportunity for interested parents to participate. This involves recruiting through a variety of public hospitals, CP-related organisations, and potentially social media sites relevant to parents of children with CP. In hospitals, relevant clinicians have agreed to develop recruitment protocols that introduce the study details and provide mechanisms to register interest in the study. In other settings, flyers/promotional letters will be disseminated with contact details of the researchers for interested participants.

Following registration of interest by individuals, they will contacted by researchers to assess eligibility for participation. After provision of written informed consent, parents will be asked to complete all baseline measures, including recording a parent-child interaction for observation, before being randomly allocated to either intervention or control.

Randomisation will be applied using a computer-generated block randomisation. The initial randomisation sequence will be managed by an individual outside of the study. Following recruitment, the research manager will determine each participant's status by opening an opaque envelope. Although the researchers will not be involved in the initial creation of the randomisation sequence, due to the study design they will not be blind to participants' condition status. Families allocated to the PACT condition will then receive access to the PARENT101 course for immediate enrolment and the control condition participants will be advised of their timelines. In the interests of equity and retaining participants, the control condition participants will be offered access to the course after completion of the post review assessment.

Assessment will be conducted at baseline, post review (10 weeks after course commencement), and at 6-months post intervention follow up. All written assessment measures will be completed by parents. Parents will also have the opportunity to provide course evaluation feedback after each module and at the end of the review session.

Measures

Family Background Questionnaire will be developed, tailoring existing standardised measures to assess general demographic variables such as SES and parental education and family factors specific to the CP context.

Gross Motor Function Classification System (GMFCS) is a parent rating measure using a 5-level system to classify children into their age-specific gross motor ability (Palisano, 1997).

It is valid and reliable and frequently used to classify functional abilities of children with physical disability.

Emotional Availability Scales (EAS; Biringen, Fidler, Barrett, & Kubicek, 2005; Biringen, Robinson, & Emde, 1998). Parents will be asked to video record a 20-minute naturalistic observation of the parent-child relationship in the home. Families will be able to send their recordings through a secure File Transfer Protocol (FTP) connection. It will be scored by an independent rater, blind to the intervention condition, using the EAS. The independent rater will be trained in the EAS. The EAS is a dyadic measure, that is, it measures the quality of the relationship itself across six scales: parental sensitivity, parental structuring, parental nonintrusiveness, parental nonhostility, child responsiveness and child involvement. The EAS also generates a global relationship quality rating. The scale has high inter-rater reliability for parental responsiveness (.96), involving (.87), sensitivity (.93) and structuring (.76).

Interpersonal Mindfulness in Parenting Scale (IM-P; Duncan, 2007) is a 10-item measure of a parent's ability to maintain present-centred attention and emotional awareness during parent-child interactions. Parents respond on a 5-point Likert scale to a series of statements. The IM-P produces four subscales: present-centred attention in parenting, present-centred emotional awareness in parenting, non-reactivity/low-reactivity in parenting and non-judgemental acceptance in parenting. The IM-P has adequate concurrent and discriminant validity (Duncan, Coatsworth, & Greenberg, 2009)

Emotional Availability-Self Report (EA-SR; Vliegen, Luyten, & Biringen, 2009) is a 32-item parent-report measure of emotional availability within the parent-child relationship. It has excellent reliability and validity. The EA-SR produces five subscales: mutual attunement, affect quality, capacity to involve the parent, intrusiveness and hostility.

Acceptance and Action Questionnaire (AAQ-7; Bond & Bunce, 2003). This 7-item version of the Acceptance and Action Questionnaire measures experiential avoidance, i.e., attempts to control the form, frequency or situational sensitivity of private events such as memories, cognitions and emotions, particularly when doing so causes harm. It produces a single total scale and can be scored either so thathigh scores reflect high experiential acceptance or so that high scores reflect high experiential avoidance. A series of statements is rated on a 7-point scale. The AAQ has satisfactory internal consistency (α= .79).

Depression Anxiety Stress Scale (DASS-21; Lovibond & Lovibond, 1995) is a 21-item questionnaire that assesses symptoms of depression, anxiety, and stress in adults. Respondents rate items on a 4-point Likert scale reflecting how much the statement applied to them in the past week. The DASS produces three subscales each with good internal consistency: the depression (α=.91), anxiety (α =.84), and stress (α=.90) scales. The DASS also has good discriminant and concurrent validity (Brown, Chorpita, Korotitsch, & Barlow, 1997; Lovibond & Lovibond, 1995).

Personal Wellbeing Index (PWI; International Wellbeing Group, 2013) is an 8-item measure of personal wellbeing in adults. Respondents rate their degree of satisfaction with various domains of living on a 10-point Likert scale. The responses are summed to create an average score representing subjective wellbeing. Respondents can also be asked to rate their life as a whole. The PWI has good validity and internal consistency (α>.70; Lau, Cummins & McPherson, 2005; International Wellbeing Group, 2013).

Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997) is a 25-item parent-report measure of child behaviour and adjustment in which the frequency of behaviours is rated on a 3-point Likert scale. The SDQ produces five subscales: emotional symptoms, conduct problems, inattention/hyperactivity, peer problems and prosocial behaviour (range 0-10). It produces a total difficulties score (range 0-40) that has been found to have adequate internal

reliability (α =.76) and test-retest reliability (*r* =.86) as well as discriminant and concurrent validity (Goodman & Scott, 1999). The SDQ is widely used in CP research (Parkes et al., 2009; Parkes et al., 2008).

CP QOL-Child (Waters et al., 2007) is a 66-item parent-report measure of child quality of life that is specifically developed for use in children with CP. It measures quality of life across several aspects of the child's life: physical wellbeing, social wellbeing, emotional wellbeing, school, service access and social acceptance. Higher scores on each scale reflect a higher quality of life in that domain. It has good concurrent validity, internal consistency (α = .76-.89) and test-retest reliability (*r* = .80-.90).

What Do Parents Think of PACT?

A key aspect of the study is ongoing parental evaluation of the course and its suitability for their situation. Client satisfaction with PARENT101 content and format will be measured using questions embedded into the course after completion of each module and review. The questions will ask parents to rate various aspects of PARENT101 on 10-point Likert scales as well as give qualitative feedback. This feedback will be examined in light of unintended adverse effects and appropriate steps will be taken if any are noted.

Data Management

Questionnaire data will be collected online through Qualtrics and uploaded into SPSS. Observational data will be entered manually. All data will be stored in securely on the university network.

Statistical Analysis

Analysis will follow standard methods for randomised controlled trials using comparisons between the two groups. Initially the two groups will be assessed to determine if they differ on key variables at baseline and covariates will be used to control for this in post-intervention analyses if necessary. The protocol of intention-to-treat analysis will be followed

in order to minimise inflation of treatment effects consistent with CONSORT guidelines. The experimental unit will be the family represented by parent-reported data. Attrition analysis will be conducted, although strategies will be used in order to minimise missing data and attrition. Data will be analysed using SPSS. The hypotheses relating to intervention efficacy will be tested using general linear models, specifically via ANOVA or ANCOVA. Where continuous data exhibit substantial skewness not overcome by transformation, non-parametric methods will be used for simple comparisons.

Ethics and Dissemination

Full ethical approval has been obtained by the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/15/QRCH/115) and The University of Queensland (2015001743). This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616000351415). Study results will be disseminated through publication in scientific journals and presentation at relevant conferences as well as directly to research participants. If efficacious, PARENT101 has the potential to be widely disseminated.

Discussion

This study aims to evaluate whether an innovative, flexible, easily accessible, and translatable course grounded in ACT and created using the edX platform for online delivery, will be efficacious in enhancing the parent-child relationship in families with children with CP. Specifically, we expect to see changes in emotional availability in a dyadic interaction, improvements in parental adjustment and wellbeing, in child functioning, adjustment, and quality of life, and increased parent psychological flexibility and interpersonal mindfulness. Parents will be randomly allocated to intervention or control condition and will be assessed at baseline, post intervention review, and at a 6-month follow up. Data will be analysed using standard CONSORT methods to evaluate efficacy in an RCT.

If found to demonstrate efficacy, the PARENT101 course has the potential to be disseminated widely in an accessible manner at minimal cost and may also provide a blueprint for use of similar online courses with parents in a full range of contexts and situations. In addition, this course could also be provided to organsiations and services as a means of providing support to those parents who may not be able to access traditional forms of face to face assistance.

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Author contributions:

The first author, Dr Koa Whittingham took a lead role in designing this study and writing the protocol. Both Dr Koa Whittingham and Dr Jeanie Sheffield, working together, created PARENT101. Dr Jeanie Sheffield and Professor Roslyn Boyd both contributed their expertise on study design and contributed to drafts of the protocol.

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Competing interests statement:
All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	N/A V1
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A no role
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-9
	6b	Explanation for choice of comparators	4-9
Objectives	7	Specific objectives or hypotheses	9
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10-12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	10-11
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11-12

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10-11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15-16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15-16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15-16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11-12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Parenting Acceptance and Commitment Therapy: A randomised controlled trial of an innovative online course for families of children with Cerebral Palsy

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Parenting Acceptance and Commitment Therapy: A randomised controlled trial of an innovative online course for families of children with Cerebral Palsy

Koa Whittingham[1,2], Jeanie Sheffield[2], & Roslyn N. Boyd[1]

[1]Queensland Cerebral Palsy and Rehabilitation Research Centre, School of Medicine, The University of Queensland, Brisbane, Australia;
[2] School of Psychology, The University of Queensland, Brisbane, Australia.

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None

Address for Correspondence:
Dr Koa Whittingham Queensland Cerebral Palsy and Rehabilitation Research Centre, The University of Queensland
Level 6, Centre for Children's Health Research
62 Graham Street South Brisbane 4101
Email: koawhittingham@uq.edu.au

Abstract

Introduction Cerebral Palsy (CP) impacts upon the entire family in a manner that is long-term, complex and multifactorial. In addition, the quality of the parent-child relationship impacts on many and varied child outcomes, making the provision of easily accessible and evidence-based support to parents of children with CP a priority. This paper reports the protocol of a randomised controlled trial of an innovative and translatable online intervention, Parenting Acceptance and Commitment Therapy (PACT), for families of children with CP. We predict that participating in the PACT program will be associated with improvements in the parent-child relationship, in child functioning, and in adjustment and quality of life for both parent and child.

Methods and analysis We aim to recruit 66 parents of children (2-10 years old) diagnosed with CP to this study. Families will be randomly assigned to two groups: waitlist control and PACT. PACT is a parenting intervention grounded in Acceptance and Commitment Therapy (ACT) and developed into an online course 'PARENT101 Parenting with Purpose' using the edX platform. All participants will be offered PACT before completion of the study. Assessments will take place at baseline, following completion of PACT and at six-month follow up (retention) and will focus on the parent-child relationship, parent and child adjustment and parent and child quality of life. Analysis will follow standard methods for randomised controlled trials using general linear models, specifically ANOVA or ANCOVA.

Ethics and dissemination Ethics approvals have been obtained through the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/15/QRCH/115) and The University of Queensland (2015001743). If efficacy is demonstrated, then the PARENT101 course has the potential to be disseminated widely in an accessible manner and at minimal cost. Further, the PACT framework may provide a blueprint for similar online courses with parents in a full range of contexts.

Registration details This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616000351415).

Keywords: cerebral palsy; online intervention; acceptance and commitment therapy; parenting

Strengths and limitations of this study

Strengths:

- This is a randomised controlled trial using CONSORT methodology
- Assessment includes a parent-child observation coded by blinded coders
- The use of online technology allows for greater flexibility in access and delivery of PARENT101
- PARENT101 course has the potential to be disseminated widely in an accessible manner at minimal cost

Weaknesses:

- The control condition is a wait-list control and will have access to PARENT101 after the completion of post-course assessments for ethical reasons
- Participants cannot be blinded to condition

Cerebral Palsy (CP) Is Not Just a Physical Disability

Motor impairments are the clinical hallmark of CP, however, other impairments are common [1]. Further, the optimal development of children with CP — psychological, social, emotional and cognitive development — is at risk. One in four children with CP have a behavioural disorder [1] compared to one in 10 typically developing children [2]. Seven in 10 preschool children with CP show significant delay in social milestones relative to community norms with continued social difficulties at school age [3-5]. One in five preschool children with CP show a significant delay in self-care skills [5]. In the long-term, focussing on adults with CP without intellectual impairment, one in five have not completed high school, four in ten are not living independently, one in two are not competitively employed, and two in three are not in a long-term relationship [6]. Families want support and solutions, however, families receive little support in optimising their children's psychological, social, emotional and cognitive development or in optimising child quality of life. Increases in parental responsiveness are a key factor in predicting child developmental benefits of early intervention [7] suggesting that parents themselves are pivotal to optimising child development.

Impact of CP on the Whole Family

CP impacts upon the entire family in a manner that is long-term, complex and multifactorial. The birth of a child with CP may precipitate complex care responsibilities, financial hardship, limits to occupational attainments, relationship distress, grief, and social isolation, all of which have further flow-on effects for parent, child and family [8]. In particular, mothers of children with CP experience greater parental stress than mothers of typically developing children [9]. They are four times more likely to have elevated anxiety symptoms and five times more likely to have moderate depressive symptoms [10, 11]. In a cross-sectional study of 818 families of children (8-12 years) with CP living across Europe,

parents were five times more likely to be experiencing very high stress levels than the general population. Interestingly, the magnitude of parenting stress was not associated with severity of motor impairment of the child [12], rather parenting stress was associated with child behavioural and emotional problems [13-16]. Parents commonly experience an ongoing grieving process, with grief intensifying during transitions and major child and family life events[17]. Parents of children with CP parent in an emotional context that may include significant stress, ongoing grief, a loss of typical parenting rewards (e.g., seeing your child walk for the first time), anxiety about the future and a lack of understanding from the broader community.

The developmental abilities of children impact upon the quality of parental caregiving that the child is able to elicit within day to day interactions [18]. Children with neurodevelopmental disabilities, who most benefit from optimal parental support, are unable to effectively elicit optimal parental support. Parents of children with CP need to be pro-active, skilled and conscious in their moment by moment parenting choices to provide their children with optimal developmental support. Parenting a child with CP, and optimising their development, involves forward thinking, scaffolding abilities, a commitment to supervision, patience, compassion, behavioural management skills, and effort above and beyond the optimal parenting of typically developing children. Further, all of that requires a strong and loving emotional bond and parental psychological resilience.

Parental Responsiveness Fuels Development

The quality of the parent-child relationship is important for all children, regardless of individual characteristics, and impacts greatly upon diverse child outcomes, including developmental, emotional, cognitive, behavioural, relational, educational, and quality of life outcomes [19-22]. A meta-analysis demonstrated that parent-child relationships with high parental responsiveness — prompt, child-directed, contingent and appropriate parenting —

are associated with improved cognitive, emotional, behavioural and social outcomes [23]. Children who have experienced a warm and emotionally available parent-child bond are more likely to be socially competent and emotionally well-adjusted, establishing stable relationships in later life [24]. Crucially, language, cognitive reasoning and pre-academic skills are learnt through the day to day interactions of the parent-child relationship. In a longitudinal observational study with 42 families, the quality of everyday parent-child interactions in the first three years of life was found to predict 61% of the variance in rates of vocabulary growth and use, as well as 59% of the variance in a child's Standford Binet IQ score at age three [25]. During everyday relationship-driven encounters, parents provide hour after hour of environmental enrichment: rich, quality experience in verbal skills, cognitive reasoning and playful exploration. Parental responsiveness can be conceptualised as nature's dose-control system for environmental enrichment [26], enabling the child to obtain 'just right' stimulation for learning and development organically in day to day life via parent-child interaction and the flow-on effects of such interaction. Nowhere is this more important than in the parent-child relationships of children with developmental delays or disabilities. These relationships may be built and enhanced through the targeted assistance of various psychological approaches.

Acceptance and Commitment Therapy (ACT): a Promising Approach

Acceptance and Commitment Therapy (ACT, said as the word 'act') is now an accepted part of the broad cognitive behavioural therapy approach (CBT). ACT incorporates: mindfulness or deliberate nonjudgmental attention to moment to moment experience, experiential acceptance or ongoing nonjudgmental contact with psychological events such as difficult emotions, cognitions and memories, and vital living or engagement in meaningful, values-driven activities [27]. The goal of ACT is to increase psychological flexibility: the ability to persist or change one's behaviour, with full awareness of the situational context and

one's own present-moment experience, in the service of chosen values. ACT, and related psychological therapies, have a growing evidence base for a diverse range of issues, e.g., occupational stress, depression, anxiety and smoking cessation [28-31]. Meta-analyses, examining the efficacy of ACT and related psychological therapies with varying dosages (30.0 ± 29.8 hours in [30]), targeting a variety of issues, have identified moderate effect sizes ranging from 0.5 to 0.75 [28-31]. Psychological flexibility, the clinical target of ACT, predicts levels of parental psychological symptoms, experienced parenting burden and symptoms of grief in parents of children with CP [17], as well as parental psychological symptoms, maternal bonding and responsiveness in mothers of infants born preterm [32].

Face to Face Parenting Intervention Incorporating ACT is Beneficial

A parenting intervention incorporating ACT was shown to be efficacious within a three-group RCT [33-35]. Sixty-seven parents of children (mean age 5.3) with CP participated in the trial. Parents were randomly assigned to: waitlist control, the parenting intervention Stepping Stones Triple P or to a combined Stepping Stones Triple P and ACT group. Families receiving Stepping Stones Triple P alone, compared to wait-list, showed improvements in child behaviour and emotional symptoms. Families receiving the combined Stepping Stones Triple P and ACT intervention, compared to wait-list control, showed improvements in child behaviour, child hyperactivity, child functional mobility performance, child quality of life, parenting style and parental adjustment. During the RCT, face to face delivery was identified as a barrier to effective translation requiring an innovative solution to capitalise on the potential benefits from the ACT-based approach.

Online Therapy Is Effective and Translatable

A meta-analysis of web-based psychological therapy indicates that web-based delivery is effective with an average effect size across intervention types and measures of 0.53 consistent with a medium effect and with greater effect sizes of 0.83 for cognitive

behavioural interventions [36]. Further, 14 RCTs were identified that directly compared web-based psychological therapy with traditional face to face psychological therapy and no significant differences between the two treatment modalities could be found. Online delivery modalities may be an ideal vehicle for low-cost and sustainable knowledge translation directly to parents in all situations, but specifically those families with children with disabilities who may require extra time and assistance therefore reducing the capacity to access traditional forms of support.

If found effective, PACT could be easily and rapidly disseminated population wide. Potentially, families of children with CP, in different countries could access immediate evidence-based psychological support, from first receiving diagnosis onwards, to promote parent and child flourishing and to harness existing strengths within the parent-child relationship to foster long-term developmental gains for the child. PACT is flexible, and family-centred, leveraging the understanding, skills and the day to day interactions that already exist within the family system for the benefit of both child and family and placing the parents as the central experts in their own child's behaviour.

Aim

Our aim is to demonstrate the efficacy of an innovative, translatable-by-design online parenting support package: Parenting Acceptance and Commitment Therapy (PACT, said as the word 'PACT') for families of young children (2 to 10 years of age) with CP. PACT will be delivered in the form of an online course for parents: PARENT101: Parenting with Purpose.

Hypotheses

We predict that participating in the PACT course, PARENT101: Parenting with Purpose, will be associated with improvements in the parent-child relationship and in both parent and child adjustment and quality of life. Following baseline assessment, outcomes

will be assessed post-intervention after the final review session and at 6 months post-intervention (retention of treatment effects).

Methods and Analysis

Design

The study is a randomised controlled trial following CONSORT (Consolidated Standards of Reporting Trials) guidelines. Parents of children with CP will be randomly allocated to one of two groups:

(1) Online Parenting Acceptance and Commitment Therapy (PACT) in the form of the online course: PARENT101: Parenting with Purpose

(2) Wait-list control

Follow up will occur at six months post intervention (retention). The wait-list condition will be offered the intervention after completion of the review assessment.

Recruitment

We aim to recruit 66 parents of children (2 to 10 years old) diagnosed with CP. Families of children with CP will be recruited through the Queensland Cerebral Palsy and Rehabilitation Research Centre, hospitals around Australia, the Australian Cerebral Palsy Register and word of mouth. As PACT uses online delivery, there are no impediments to participants being recruited from across Australia including in regional areas, making this project highly feasible.

Exclusion criteria: as PACT uses integrated web-based delivery, parents are required to have: (1) reliable internet access at home (e.g., ADSL) and be committed to maintaining internet access for the duration of the study; (2) a mobile phone for receiving text messages that they are asked to check regularly throughout the study; (3) an email address for receiving

emails that they are asked to check several times a week throughout the study; and (4) access to Skype.

Sample size. To have sufficient power to detect an effect size of 0.40 (power 0.8) a total sample size of 52 is required. If a conservative retention rate of 80% is assumed this leads to a total of 66 families to be recruited.

The PACT Intervention

PACT includes ACT techniques already established in an RCT as effective with families of children with CP, including mindfulness, experiential acceptance and cognitive defusion [33-35]. It includes some techniques from the established parenting literature but focuses on strategies to enhance the parent-child relationship and promote parental emotional responsiveness. An online course was created using the edX platform, an open source course management system created by founding partners Harvard and MIT (www.edx.org/). The edX platform is used to host Massive Open Online Courses (MOOCs) and allows for the online delivery of a variety of educational courses that can be accessed from anywhere that has internet availability.

Within the edX framework, the PACT program has been developed to give it the look and accessibility of a course and has been named PARENT101: Parenting with Purpose. PARENT101 incorporates: virtual written text, video presentations, screen-based interactive activities, journal activities, reflections, guided experiential and mindfulness exercises and participation in a moderated discussion board. In addition, research participants will be offered Skype sessions with a therapist as well as reminder text messages and emails. PARENT101 is presented as three modules plus a review session 4 weeks after the final module. Modules are scheduled to be completed each fortnight, with a four-week break after that to allow for practise of the materials from the course. Overall the course lasts for 10 weeks (6 weeks for modules plus review 4 weeks later) in total, with parents able to move

through each module's content with some flexibility. Access to PARENT101 will be restricted to study participants until efficacy is established.

Study Procedure

After obtaining ethical approval, a recruitment strategy was developed to maximise opportunity for interested parents to participate. This involves recruiting through a variety of public hospitals, CP-related organisations, and potentially social media sites relevant to parents of children with CP. In hospitals, relevant clinicians have agreed to develop recruitment protocols that introduce the study details and provide mechanisms to register interest in the study. In other settings, flyers/promotional letters will be disseminated with contact details of the researchers for interested participants.

Following registration of interest by individuals, they will contacted by researchers to assess eligibility for participation. After provision of written informed consent, parents will be asked to complete all baseline measures, including recording a parent-child interaction for observation, before being randomly allocated to either intervention or control. Randomisation will be applied using a computer-generated block randomisation. The initial randomisation sequence will be managed by an individual outside of the study. Following recruitment, the research manager will determine each participant's status by opening an opaque envelope. Although the researchers will not be involved in the initial creation of the randomisation sequence, due to the study design they will not be blind to participants' condition status. Families allocated to the PACT condition will then receive access to the PARENT101 course for immediate enrolment and the control condition participants will be advised of their timelines. In the interests of equity and retaining participants, the control condition participants will be offered access to the course after completion of the post review assessment.

Assessment will be conducted at baseline, post review (10 weeks after course commencement), and at 6-months post intervention follow up. All written assessment measures will be completed by parents. Parents will also have the opportunity to provide course evaluation feedback after each module and at the end of the review session.

Measures

Family Background Questionnaire will be developed, tailoring existing standardised measures to assess general demographic variables such as SES and parental education and family factors specific to the CP context.

Gross Motor Function Classification System (GMFCS) is a parent rating measure using a 5-level system to classify children into their age-specific gross motor ability [37]. It is valid and reliable and frequently used to classify functional abilities of children with physical disability.

Emotional Availability Scales (EAS; [38, 39]) The EAS is the primary outcome measure. Parents will be asked to video record a 20-minute naturalistic observation of the parent-child relationship in the home. Families will be able to send their recordings through a secure File Transfer Protocol (FTP) connection. It will be scored by an independent rater, blind to the intervention condition, using the EAS. The independent rater will be trained in the EAS. The EAS is a dyadic measure, that is, it measures the quality of the relationship itself across six scales: parental sensitivity, parental structuring, parental nonintrusiveness, parental nonhostility, child responsiveness and child involvement. The EAS also generates a global relationship quality rating. The scale has high inter-rater reliability for parental responsiveness (.96), involving (.87), sensitivity (.93) and structuring (.76).

Interpersonal Mindfulness in Parenting Scale (IM-P; [40]) is a 10-item measure of a parent's ability to maintain present-centred attention and emotional awareness during parent-child interactions. Parents respond on a 5-point Likert scale to a series of statements. The IM-P

produces four subscales: present-centred attention in parenting, present-centred emotional awareness in parenting, non-reactivity/low-reactivity in parenting and non-judgemental acceptance in parenting. The IM-P has adequate concurrent and discriminant validity [41].

Emotional Availability-Self Report (EA-SR; [42]) is a 32-item parent-report measure of emotional availability within the parent-child relationship. It has excellent reliability and validity. The EA-SR produces five subscales: mutual attunement, affect quality, capacity to involve the parent, intrusiveness and hostility.

Acceptance and Action Questionnaire (AAQ-7; [43]). This 7-item version of the Acceptance and Action Questionnaire measures experiential avoidance, i.e., attempts to control the form, frequency or situational sensitivity of private events such as memories, cognitions and emotions, particularly when doing so causes harm. It produces a single total scale and can be scored either so that high scores reflect high experiential acceptance or so that high scores reflect high experiential avoidance. A series of statements is rated on a 7-point scale. The AAQ has satisfactory internal consistency (α= .79).

Depression Anxiety Stress Scale (DASS-21; [44]) is a 21-item questionnaire that assesses symptoms of depression, anxiety, and stress in adults. Respondents rate items on a 4-point Likert scale reflecting how much the statement applied to them in the past week. The DASS produces three subscales each with good internal consistency: the depression (α=.91), anxiety (α =.84), and stress (α=.90) scales. The DASS also has good discriminant and concurrent validity (Brown, Chorpita, Korotitsch, & Barlow, 1997; Lovibond & Lovibond, 1995).

Personal Wellbeing Index (PWI; [45]) is an 8-item measure of personal wellbeing in adults. Respondents rate their degree of satisfaction with various domains of living on a 10-point Likert scale. The responses are summed to create an average score representing subjective wellbeing. Respondents can also be asked to rate their life as a whole. The PWI has good validity and internal consistency (α>.70; [45, 46]).

Strengths and Difficulties Questionnaire (SDQ; [47]) is a 25-item parent-report measure of child behaviour and adjustment in which the frequency of behaviours is rated on a 3-point Likert scale. The SDQ produces five subscales: emotional symptoms, conduct problems, inattention/hyperactivity, peer problems and prosocial behaviour (range 0-10). It produces a total difficulties score (range 0-40) that has been found to have adequate internal reliability (α =.76) and test-retest reliability (*r* =.86) as well as discriminant and concurrent validity[48] . The SDQ is widely used in CP research [49, 50].

CP QOL-Child [51] is a 66-item parent-report measure of child quality of life that is specifically developed for use in children with CP. It measures quality of life across several aspects of the child's life: physical wellbeing, social wellbeing, emotional wellbeing, school, service access and social acceptance. Higher scores on each scale reflect a higher quality of life in that domain. It has good concurrent validity, internal consistency (α = .76-.89) and test-retest reliability (*r* = .80-.90).

What Do Parents Think of PACT?

A key aspect of the study is ongoing parental evaluation of the course and its suitability for their situation. Client satisfaction with PARENT101 content and format will be measured using questions embedded into the course after completion of each module and review. The questions will ask parents to rate various aspects of PARENT101 on 10-point Likert scales as well as give qualitative feedback. This feedback will be examined in light of unintended adverse effects and appropriate steps will be taken if any are noted.

Data Management

Questionnaire data will be collected online through Qualtrics and uploaded into SPSS. Observational data will be entered manually. All data will be stored in securely on the university network.

Statistical Analysis

Analysis will follow standard methods for randomised controlled trials using comparisons between the two groups. Initially the two groups will be assessed to determine if they differ on key variables at baseline and covariates will be used to control for this in post-intervention analyses if necessary. The protocol of intention-to-treat analysis will be followed in order to minimise inflation of treatment effects consistent with CONSORT guidelines. The experimental unit will be the family represented by parent-reported data. Attrition analysis will be conducted, although strategies will be used in order to minimise missing data and attrition. Data will be analysed using SPSS. The hypotheses relating to intervention efficacy will be tested using general linear models, specifically via ANOVA or ANCOVA. Where continuous data exhibit substantial skewness not overcome by transformation, non-parametric methods will be used for simple comparisons.

Ethics and Dissemination

Full ethical approval has been obtained by the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/15/QRCH/115) and The University of Queensland (2015001743). This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616000351415). Study results will be disseminated through publication in scientific journals and presentation at relevant conferences as well as directly to research participants. If efficacious, PARENT101 has the potential to be widely disseminated.

Discussion

This study aims to evaluate whether an innovative, flexible, easily accessible, and translatable course grounded in ACT and created using the edX platform for online delivery, will be efficacious in enhancing the parent-child relationship in families with children with CP. If found to demonstrate efficacy, the PARENT101 course has the potential to be disseminated widely in an accessible manner at minimal cost and may also provide a

blueprint for use of similar online courses with parents in a full range of contexts and situations. In addition, this course could also be provided to organisations and services as a means of providing support to those parents who may not be able to access traditional forms of face to face assistance.

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Author contributions:
The first author, Dr Koa Whittingham took a lead role in designing this study and writing the protocol. Both Dr Koa Whittingham and Dr Jeanie Sheffield, working together, created PARENT101. Dr Jeanie Sheffield and Professor Roslyn Boyd both contributed their expertise on study design and contributed to drafts of the protocol.

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Competing interests statement:
All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	N/A V1
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A no role
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-9
	6b	Explanation for choice of comparators	4-9
Objectives	7	Specific objectives or hypotheses	9
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10-12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	10-11
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11-12

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10-11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15-16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15-16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15-16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11-12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.