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Evaluating an early, novel online intervention ('Family Focus') with and without coaching for primary carers of children with developmental regression

Submission date 15/05/2025	**Recruitment status** Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 20/05/2025	**Overall study status** Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 15/12/2025	**Condition category** Mental and Behavioural Disorders	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Developmental regression–when a child loses skills they previously had–can be very distressing for families and is usually linked to poorer outcomes for children. In Australia, there is currently no quick way for families to get assessment and support for children showing signs of developmental regression. This study aims to find out how effective and widely used a combined coaching and online program is in reducing parental stress compared to the online program alone. The online program, called Family Focus, is designed to empower parents of children with developmental regression by giving them resources and support to improve the wellbeing and participation of their child and family.

Who can participate?

Parents who have a child aged 1–15 years old who has lost skills in one or more areas (such as language, thinking, social-emotional, or motor skills) in the last 18 months, and who currently live in Victoria, Australia.

What does the study involve?

Participants are asked to join the study when they attend the Developmental Regression clinic at Monash Children's Hospital in Victoria, Australia. Participants are randomly assigned to one of two groups. One group will access the Family Focus online program. The other group will access the Family Focus program and up to 12 online coaching sessions with a health professional over 6 months (each session lasting up to 45 minutes).

All participants will have access to the Family Focus program that consists of 10 interactive online modules, 6 podcasts, and other resources. Participants will also complete online questionnaires three times during the study.

What are the possible benefits and risks of participating?

Participants will receive information and resources to support their own wellbeing as a carer, as well as their child’s and family’s health and participation. The main risk is that some of the questionnaires or program content may be upsetting or triggering for some participants. There are features such as warnings to flag potentially concerning content, and helplines to assist participants who might experience feelings of grief or trauma. When appropriate, a research staff member will also recommend next steps, such as contacting a GP or seeking assistance from the emergency department.

Where is the study running from?
Monash University and Monash Children's Hospital, Australia

When is the study starting and how long is it expected to run for?
December 2025 to June 2027

Who is funding the study?
The study is funded by a Medical Research Future Fund (MRFF) grant from the Australian Government Department of Health and Aged Care.

Who is the main contact?
Monica Leo (trial coordinator)
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Additional identifiers

Protocol serial number
RES-24-0000-300A, 107806

Study information

Scientific Title
A pragmatic parallel-group randomised controlled trial to evaluate the effectiveness of coaching with an online intervention, compared to the online intervention alone, for families of children who have experienced developmental regression

Study objectives
It is hypothesised that at post-intervention (6 months post-randomisation) and 6 months follow-up (12 months post-randomisation):
1. Parents in the Coaching + Family Focus (‘intervention group’) will report lower parental stress (primary outcome), anxiety and depressive symptoms (secondary outcomes) compared with parents in the Family Focus (‘comparison group’).
2. Parents in the Coaching + Family Focus group will report greater improvements in family empowerment, family quality of life, and engagement in health-promoting activities (all secondary outcomes) compared with parents in the Family Focus group.

3. Clinicians will report greater improvement and lower severity in the child's global health (secondary outcomes) among children whose parents are in the Coaching + Family Focus group compared to children whose parents are in the Family Focus group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/08/2024, Monash Health Human Research Ethics Committee (Research Support Services, Monash Health, Level 2, I Block, Monash Medical Centre, 246 Clayton Road, Clayton, Victoria 3168, Australia; +61 39594 4611; research@monashhealth.org), ref: HREC/107806 /MonH-2024-442837

Study design
Single-center single-blind interventional superiority randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Health and wellbeing of parents (or other primary carers) of children with developmental regression

Interventions
There are two components being tested:
1. The Family Focus program (online intervention)
2. Coaching delivered via videoconferencing

Parent participants will be randomly assigned to one of two groups using the randomisation module in REDCap. One will engage in the Family Focus program with coaching over 6 months, another group will engage in the program without coaching.

The Family Focus program
The Family Focus program is developed as an online intervention for parents caring for children experiencing developmental regression. The program consists of 10 self-paced online modules and 6 podcasts that incorporate evidence-informed topics and content codesigned with clinicians and parents with lived or living experience caring for children with developmental regression. The modules and podcasts cover a range of topics, including (but not limited to) parent mental health and wellbeing, supporting their child's development, and making connections with their communities. Participants in both groups will have access to the Family Focus program for the duration of the trial. To enhance program adherence and engagement, nudges and reminders in the form of email and text messages will be delivered based on parents' preferences in the first 6 months before the post-intervention assessment.

Coaching
One-on-one coaching will be delivered by a trained health professional coach for up to 45 minutes per session, for a maximum of 12 sessions over 6 months, depending on the need and preference of parents. Coaching will be individualised, with the parents identifying the priorities

and goals that are important to them and their family. The focus will be on improving the overall child and family functioning, wellbeing and participation of the child and the family. When parents identify goals related to the content of the Family Focus program, the coach will help them reflect on the relevant online content. The coach will also guide parents in identifying the supports, resources and skills they already have to help them work towards their goals, and assist them in choosing manageable actions they can take. Coaching will be delivered using a strengths-based approach that includes collaborative planning, observation, reflection, action and feedback.

Intervention Type

Behavioural

Primary outcome(s)

Parent stress, measured using the Stress subscale of the Depression Anxiety Stress Scales (DASS-21), at post-intervention and 6-month follow-up.

Key secondary outcome(s))

1. Parent anxiety and depressive symptoms, measured using the Depression and Anxiety subscales of the DASS-21, at post-intervention and 6-month follow-up
2. Family empowerment, measured using the Family Empowerment Scale, at post-intervention and 6-month follow-up
3. Family quality of life, measured using the Beach Center Family Quality of Life Scale, at post-intervention and 6-month follow-up
4. Parent engagement in health-promoting activities, measured using the Health Promoting Activity Scale, at post-intervention and 6-month follow-up
5. Child global health outcomes, measured using the Clinical Global Impression-Severity (CGI-S) and CGI-Improvement (CGI-I) scales, at post-intervention and 6-month follow-up
6. Program uptake and engagement will be examined using metrics including the number of modules/podcasts viewed, the number of tipsheet downloads, the number of goals identified and worked toward, and parental ratings of module usefulness and satisfaction at post-intervention
7. Coaching uptake and engagement will be examined using metrics including the number of coaching sessions completed, the percentage of coaching sessions elected by participants out of the maximum of 12, and parental ratings of coaching sessions at post-intervention.

Completion date

30/06/2027

Eligibility

Key inclusion criteria

Parents:
1. With children aged between 1-15 years with suspected or confirmed loss of skills in one or more developmental domains (language, cognitive, social-emotional, motor) within the 18 months before their first visit to the Developmental Regression clinic
2. Live in Victoria, Australia
3. Are comfortable in reading English at a Grade 7 level
4. Have access to an internet-enabled device
5. Have an active email account

Participant type(s)

Carer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Parents whose children have:
1. A history of skill loss that cannot be verified through developmental surveillance records, clinical assessments, or video or audio recordings
2. Developmental regression took place in the context of significant environmental adversity (e.g. maltreatment, domestic violence, housing instability)
3. A condition that requires urgent medical intervention and stabilisation

Date of first enrolment
12/12/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Australia

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Sponsor information

Organisation
Monash University

ROR
https://ror.org/02bfwt286

Funder(s)

Funder type
Government

Funder Name
Department of Health and Aged Care, Australian Government

Alternative Name(s)
Australian Government Department of Health and Aged Care, Dept of Health & Aged Care, Department of Health, Australian Government Department of Health, The Department of Health, Australian Dept of Health & Aged Care, healthgovau, Department of Health and Aged Care · Aged Care, Department of Health and Aged Care, Australian Government, Australian Department of Health and Aged Care, Department of Health, Australian Government, Department of Health and Aged Care, The Department of Health and Aged Care, DHAC, DoHAC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request and approval from the study's Principal Investigator, Katrina Williams (Katrina.Williams@monash.edu).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes