FindWays: testing a co-designed website for parents to find ways to help their child's behaviour or emotions

| Submission date | Recruitment status No longer recruiting | [X] Prospectively registered | | |
|-------------------|--|---------------------------------|--|--|
| 10/06/2021 | | [X] Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 19/07/2021 | Completed | ☐ Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 17/01/2025 | Mental and Behavioural Disorders | [X] Record updated in last year | | |

Plain English summary of protocol

Background and study aims

Mental health problems are common in children. The paediatrician is one of the most common professionals that families will go to for help. However, seeing a paediatrician has drawbacks such as long waitlists, they are expensive, and they generally aren't trained to deliver evidence-based talking therapy for behavioural or emotional problems.

The aim of this study is to find out whether a new co-designed website (FindWays) is an acceptable and feasible way to try and help families find ways to help their child's behaviour or emotions while they wait to see the paediatrician. FindWays was co-designed with parents in Geelong whose children were waiting to get help from the paediatrician for a behavioural or emotional problem.

Who can participate?

Parents of children aged 2-12 years with a behavioural or emotional problem who are seeing the paediatrician for the first time

What does the study involve?

Parents are randomly allocated to use the new website (treatment group) or to not use the website (control group) and access their usual supports. The FindWays website has information to help parents find ways to help their child behaviour or emotions. This information includes different parenting strategies participants can try at home, learn what different professionals or programs can do to help their child, and where to find local and available professional help.

What are the possible benefits and risks of participating?

Parents may find the website gives them new strategies to try at home to help their child's problem or helps them access new services while they wait. This may help the child's behaviour and the parent's mental health. The risks include using a new strategy or seeing a professional who won't be able to help their child.

Where is the study run from? Murdoch Children's Research Institute (Australia) When is the study starting and how long is it expected to run for? November 2020 to May 2023

Who is funding the study?

- 1. National Health and Medical Research Council (Australia)
- 2. Murdoch Children's Research Institute (Australia)
- 3. Charity Drive Days (Australia)

Who is the main contact? Dr Daniel Peyton Daniel.peyton@mcri.edu.au

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

HREC 75854

Study information

Scientific Title

The acceptability and feasibility of a co-designed website (FindWays) for parents of children with a mental health problem: a pilot randomised controlled trial

Study objectives

It is hypothesised that FindWays is an acceptable and feasible way of potentially helping parents find ways to help their child's behaviour and emotions while they wait to see the paediatrician. As this is a pilot randomised controlled trial (RCT), it will not be powered to assess effectiveness of parent, child or health service use outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/04/2022, The Royal Children's Hospital Human Research Ethics Committee (Research Ethics & Governance, The Royal Children's Hospital Melbourne, 50 Flemington Road, Parkville, 3052, Victoria Australia; +61 (0)3 9345 5044; Rch.ethics@rch.org.au), ref: 75854

Study design

Mixed methods pilot randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Behavioural and emotional problems in children

Interventions

A statistician not directly involved in the analysis of the trial results will prepare the randomisation schedule. The randomisation schedule will be created by computer-generated random numbers, before the first participant has been recruited. The participant cohort will be stratified by child age (2-6 years old and 7-12 years old) and clinic. Within each strata, permuted block randomisation will be used to ensure balance between the website and control group. A randomly generated sequence of block sizes containing 2, 4, or 6 participants will be used. This will help ensure balance in numbers between website and control groups, prevent potential confounders of age or clinic type impacting the measurement of outcomes, and prevent any predictability in website allocation. The schedule will be held by an independent statistician, and allocation will not be revealed prematurely to CI Peyton. Because of these procedures, the research team will be unable to predict which group the participant will be allocated to.

The intervention consists of access to a new, co-designed website. This website, FindWays, offers parents relevant, credible and specific information on behavioural and emotional problems. Hopefully, this will help the parent find ways to help their child's problem while they wait to see a paediatrician, over and above their usual supports (e.g., general practitioner). This information includes different parenting strategies they can try at home, learn what different professionals or programs can do to help their child, and where to find available professional help. On a semi-regular basis, parents in the intervention group will be sent a reminder to access the website. These reminders also contain some brief information about the purpose of the website. The timing and delivery of these prompts will be decided during a co-design session.

The control group will receive routine standard care. This care is provided by usual providers (e. g. general practitioner, existing online resources, teachers at school).

Overview of the methodology:

- 1. Participants will be recruited from paediatric clinics in Geelong, Victoria. They will be recruited if they have been recently referred because of a concern about their child's behaviour or emotions
- 2. If they consent to participate and complete their baseline measures, they will then be randomised to either the intervention or control group.
- 3. Those in the intervention group will have access to the FindWays website for 4 months. They will receive semi-regular reminders about the website.
- 4. At 4 months, they will complete a second set of measures and a qualitative interview describing their experience using the website.

Intervention Type

Behavioural

Primary outcome measure

Feasibility and acceptability are measured using:

- 1. Recruitment measured by the number of eligible participants who consent to participate in the study after 3 attempts to contact within a 3-month recruitment period
- 2. Retention measured by the number of consenting participants in the intervention group who access the website as measured by Google Analytics continuously over the 4-month trial
- 3. Likelihood of recommending the intervention as measured by a Likert scale (0-10) net promoter score at 4 months

- 4. Usability and safety feedback measured by qualitative interview at 4 months
- 5. Number of participants who complete all quantitative baseline measures and final measures at 4 months
- 6. Number of participants who access the website as measured by Google Analytics within the 4-month trial period
- 7. Tasks completed on the website (e.g. parenting strategies found, suitable professionals found) measured by parent survey at 4 months

Secondary outcome measures

- 1. Child behaviour and emotions as measured by parent-reported Strengths and Difficulties Questionnaire (SDQ) at baseline and 4 months
- 2. Family impact of the child's behaviour and emotions as measured by parent-reported SDQ impact statement at baseline and 4 months
- 3. Parent mental health and distress as measured by the parent-reported Depression, Anxiety and Stress Scale (DASS-21) at baseline and 4 months
- 4. Health services use measured by parent-reported surveys at 4 months

Overall study start date

19/11/2020

Completion date

01/05/2023

Eligibility

Key inclusion criteria

- 1. Parent or carer of a child aged 2-12 years at the time of randomisation
- 2. Referred for a first appointment with a paediatrician to manage a behavioural or emotional problem
- 3. Has a behavioural or emotional problem as listed for review on the referral letter
- 4. Provide a verbal consent that is signed and dated by the researcher

Participant type(s)

Carer

Age group

Adult

Sex

Both

Target number of participants

60

Total final enrolment

34

Key exclusion criteria

- 1. Has a parent-reported diagnosis of an intellectual disability or autism spectrum disorder
- 2. Child in out of home care

3. The paediatrician decides the child needs an early review (such as for a severe problem or to exclude a medical problem)

Date of first enrolment

02/05/2022

Date of final enrolment

01/01/2023

Locations

Countries of recruitment

Australia

Study participating centre Murdoch Children's Research Institute

50 Flemington Road Parkville Australia 3052

Sponsor information

Organisation

Murdoch Children's Research Institute

Sponsor details

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Sponsor type

Research organisation

Website

https://www.mcri.edu.au/

ROR

https://ror.org/048fyec77

Funder(s)

Funder type

Government

Funder Name

National Health and Medical Research Council

Alternative Name(s)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Funder Name

Murdoch Children's Research Institute

Alternative Name(s)

MCRI

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

Australia

Funder Name

Charity Drive Days

Results and Publications

Publication and dissemination plan

The study protocol will be published through a peer-reviewed journal and made available after publication.

The results will be disseminated via four methods:

- 1. Publication of results in a high-impact peer-reviewed journal
- 2. Presentation of results to conferences
- 3. Presentation of results to local paediatricians in Geelong
- 4. Plain language summary or results to be distributed to parents agreeing to receive follow-up results

Intention to publish date

01/05/2025

Individual participant data (IPD) sharing plan

The data are not expected to be made available at an individual level. The researchers do not have ethics consent from participants to share individual-level data with other organisations. Data will be stored by the Murdoch Children's Research Institute.

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 21/03/2023 | 24/03/2023 | Yes | No |
| Participant information sheet | version 1.4 | 05/04/2022 | 02/09/2024 | No | Yes |