

# FLY-Kids feasibility

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|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Not available              |
| <b>Status</b>                | Pending                    |
| <b>Health condition type</b> | Other condition            |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON57491

### Source

Onderzoeksportaal

### Brief title

FLY-Kids: pilot and feasibility study for a digital version of FLY-Kids

### Condition

- Other condition

### Synonym

lifestyle

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Derde geldstroom (anders, zoals collectebussenfondsen, Europese Unie, vakministeries of bedrijven)

### Intervention

- Life style intervention

## Explanation

N.a.

## Outcome measures

### Primary outcome

The objective of this study is to examine the feasibility of using a digital version of FLY-Kids during a regular youth healthcare visit.

### Secondary outcome

The feasibility of using the digital version of FLY-Kids during a youth healthcare visit in different subgroups in the study population.

## Study description

### Background summary

FLY-Kids is a digital lifestyle screening tool for children aged 1–3, designed for use in youth healthcare. Parents complete 10 lifestyle-related questions before their visit, creating an overview to support discussions with YHCP. The tool also provides guidance for improving the child's lifestyle. To enhance implementation, digitalization is key. A previous study identified user needs, leading to the first digital version of FLY-Kids.

### Study objective

This feasibility study will now evaluate its use during regular visits, gathering feedback from parents and YHCP, along with user data from the digital tool.

### Study design

Onsite training in the use of FLY-Kids will be provided for YHCP.

After giving consent, parents will complete FLY-Kids digitally before their regular youth healthcare visit. They will then receive a dashboard with feedback and general lifestyle information. During the visit, their child's weight and height will be measured as part of standard care. The FLY-Kids dashboard will serve as a conversation aid for parents and YHCP to discuss the child's lifestyle, and parents will receive guidance on next steps. To evaluate the digital version of FLY-Kids, parents and YHCP will complete a questionnaire—parents

immediately after the visit and YHCP at the end of the study. Additionally, data from digital patient files will be collected, including FLY-Kids usage data and demographic information such as the child's age, sex, parents' education level, primary home language, country of birth, and number of children in the family

## **Intervention**

NA

## **Study burden and risks**

The burden for this research is minimal. The only foreseen burden is the time it takes to complete the questionnaires (FLY-Kids and evaluation). No risks will be expected.

## **Contacts**

### **Scientific**

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### **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam  
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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Babies and toddlers (28 days-23 months)  
Newborns  
Children (2-11 years)  
Adults (18-64 years)

## Inclusion criteria

Parents: Parents/caregivers of a child aged 1-4 years scheduled for a regular youth healthcare visit and can provide electronic informed consent. Youth healthcare professional (YHCP): Directly working with children aged 0-4 years and Has worked with FLY-Kids during a regular youth healthcare visit.

## Exclusion criteria

Both groups: no informed consent was obtained

## Study design

### Design

|                     |                            |
|---------------------|----------------------------|
| Study phase:        | N/A                        |
| Study type:         | Observational non invasive |
| Intervention model: | Single                     |
| Allocation:         | Non controlled trial       |
| Masking:            | Open (masking not used)    |
| Control:            | Uncontrolled               |
| Primary purpose:    | Health services research   |

### Recruitment

|                           |                        |
|---------------------------|------------------------|
| NL                        |                        |
| Recruitment status:       | Pending                |
| Start date (anticipated): | 19-03-2025             |
| Enrollment:               | 300                    |
| Duration:                 | 1 months (per patient) |
| Type:                     | Anticipated            |

## Medical products/devices used

Product type: N.a.

## IPD sharing statement

**Plan to share IPD:** Undecided

### Plan description

N.a.

## Ethics review

Not available

Date: 21-03-2025

Application type: First submission

Review commission: CCMO

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register        | ID        |
|-----------------|-----------|
| Research portal | NL-009531 |