

# **StoMakker: Improving the quality of life of children receiving an ileostomy, colostomy or continent urostomy by offering access to a peer support platform, age dependent information provision and games in a smartphone application**

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The main objective of this study is to investigate whether access to a peer support platform, age-dependent information provision and games in a smartphone application increases self-reported quality of life, for children receiving a stoma.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal inflammatory conditions
<b>Study type</b>	Interventional

## **Summary**

### **ID**

NL-OMON56322

### **Source**

ToetsingOnline

### **Brief title**

StoMakker

### **Condition**

- Gastrointestinal inflammatory conditions
- Genitourinary tract disorders NEC

### **Synonym**

Stoma

**Research involving**  
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** ZonMW,MLDS

## Intervention

**Keyword:** Children, Digital healthcare, E-Health, Stoma

## Outcome measures

### Primary outcome

Primary outcome of this study is Quality of life.

### Secondary outcome

Secondary outcomes are knowledge retention, patient satisfaction, patient skills and ability to take care of their stoma, digital literacy.

## Study description

### Background summary

Peer support, patient education and guidance are of crucial importance for children undergoing surgery for a stoma. Patients have to adapt to and cope with the new situation, which might be difficult and result in insecurities. Insecurities are reported to lead to a variety of psychosocial problems. Peer support helps to cope with the new situation and insecurities. Self-efficacy is known to be associated with a reduction of psychosocial problems and stoma-related morbidities.

### Study objective

The main objective of this study is to investigate whether access to a peer support platform, age-dependent information provision and games in a smartphone application increases self-reported quality of life, for children receiving a stoma.

## Study design

Multicentre randomized controlled trial

## Intervention

The intervention group will be asked to install the mobile application and will be provided an access code to enter the application. The application will give the participants in the intervention group access to a peer support platform, age dependent information provision, serious games, quizzes and built-in questionnaires.

## Study burden and risks

The only difference is the use of the mobile application; therefore, no additional risks are associated with participation in this trial. In the intervention group the burden of participation is restricted to the pushed-messages with information to improve self-efficacy and to register the progress of self-care or outcomes in the app. Both groups are asked to fill out several questionnaires.

## Contacts

### Public

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NL

### Scientific

Academisch Medisch Centrum

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

### Inclusion criteria

Children between 6 and 18 years old receiving surgery for the creation of a ileostomy, colostomy, or continent urostomy.

### Exclusion criteria

No access to mobile device (smartphone or tablet)

Insufficient understanding of the Dutch language

Incapability to use a mobile device due to physical disabilities

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	22-12-2022
Enrollment:	66
Type:	Actual

## Medical products/devices used

Generic name:	StoMakker
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	30-09-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-07-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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
CCMO	NL81685.018.22