### Table, Supplemental Digital Content 1:

| Outcomes                          | Completed by                                           |
|----------------------------------|--------------------------------------------------------|
| Clinical effectiveness           | All patients                                           |
| Quality of life                  | All patients and parents of patients < 18 years of age |
| Adherence (MARS)                 | All patients using TAI                                 |
| Medication beliefs (BMQ)         | All patients using TAI                                 |
| Illness perception (BIPQ)        | All patients                                           |
| Treatment satisfaction (TSQM)    | All patients using TAI                                 |
| Patient empowerment (GYPES)      | Patients ≥ 13 years old                                 |

### File, Supplemental Digital Content 2:

Subjects who were potentially eligible for the retrospective part of the study were given the opportunity to opt-out of the study. Subjects who did not opt out and were eligible for the cross-sectional part of the study, received questionnaires electronically. Patients and their parents were asked to complete several questionnaires, some of these questionnaires were filled out separately (parent-report and self-report). Children up to 12 years old were given the instructions to complete the questionnaires with the help of a parent. Completing all online questionnaires took approximately 45 minutes and was done at home. After completion of all questionnaires, subjects received a gift card worth €25.00. Patients did not receive any other forms of financial compensation.

**Participants**

We included children and adolescents up to 18 years of age, diagnosed with FC or functional non-retentive fecal incontinence according to the Rome IV criteria, or with an organic cause of constipation, who started TAI treatment with a Navina system at our institution. We included children using two separate systems: the manually controlled Navina Classic system and the electronically operated Navina Smart system. In our clinic, children who are about to start TAI treatment are informed about various TAI systems (Navina, Peristeen®, and Qufora® [MacGregor Healthcare Ltd, Macmerry, UK]) by a specialized nurse. Then, patients and their caregivers choose a system with the help of the specialized nurse. Education on how to use the system is then provided by the specialized nurse and a delegate of the manufacturer, this includes information about and guidance in the choice for a small
catheter, regular catheter, or cone. In this study, we were only able to collect data on the catheter types being used if patients completed the cross-sectional survey. Since these subgroups were small and the type of catheter was chosen together with child and parents, we did not perform additional subgroup analyses based on which catheter or cone was used. For the cross-sectional part of the study we also included children who were already using Navina systems when first seen in our clinic. Participants were excluded from the cross-sectional survey if no e-mail address was available or if they had limited Dutch language proficiency.

Quality of life

The PedsQL 4.0 Generic Core Scales were used to assess HRQoL, and the PedsQL GI symptom scales were used to assess perceptions on gastrointestinal specific symptoms (19-21). The scales used in the current study comprised of parallel child self-report and parent proxy-report formats for children aged 5 to 7 (young child), 8 to 12 (child), and 13 to 18 years old (adolescent). Both questionnaires are comprised of subscales, including a constipation-specific symptom scale. Items are reverse-scored and linearly transformed to a 0 to 100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0); higher scores indicate less problems or symptoms and, hence, a higher HRQoL. The total score and subscale scores are computed as the sum of the items divided by the number of items answered. The questionnaires were completed by all children, and parents of children under 18 years of age. Data are presented separately for children with NBD and children with FC and compared with HRQoL data of other studies reporting data of Dutch healthy children, Dutch children with FC, and American children with FC (22-24).

Treatment adherence and beliefs, and illness perceptions

The Medication Adherence Report Scale (MARS) questionnaire was used to assess treatment adherence and was completed by all children using Navina systems at time of the survey (27, 28). The questionnaire consists of 5 items scored on a 5-point Likert scale (1= always, 5 = never). This resulted in a total score ranging from 5 to 25, with higher scores implying higher adherence. Data are reported both as continuous outcomes as well as the percentage of adherent patients (defined as a MARS score of ≥23) (28). Children using Navina at time of the cross-sectional survey completed the “Beliefs about Medicines Questionnaire (BMQ) – Specific” to assess beliefs about the necessity of, and concerns about TAI (29). Both the necessity and concern subscale scores range from 5 to 25, with
higher scores representing stronger necessity perceptions and stronger concerns. All children completed the Brief Illness perceptions questionnaire (BIPO) to assess cognitive and emotional perceptions of illness(30). This questionnaire uses a single-item scale approach with 8 items which are rated on a scale from 0 to 10. Higher scores reflect stronger perceptions of the respective item.

**Patient independence and empowerment**

A self-developed questionnaire was used to measure treatment independence. Children rated the relative change in independence concerning their bowel management since start TAI on a 5-point Likert scale ranging from greatly decreased to greatly increased. Children from 13 years of age using Navina at time of the survey completed the Gothenburg Young Persons Empowerment Scale (GYPES) to assess patient empowerment (31). The questionnaire consists of 15 items scored on a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). Scores were calculated for 5 domains (Knowledge and Understanding, Personal Control, Identity, Decision making, and Enabling others) and a total empowerment score was calculated. This resulted in a total score ranging from 15 to 75, with higher scores corresponding with higher levels of empowerment.

**Treatment satisfaction and patient experience**

Children using Navina at time of the cross-sectional survey completed the Treatment Satisfaction Questionnaire for Medication (TSQM) to assess treatment satisfaction (28, 32). A self-developed questionnaire was used to evaluate patient experience with the transanal irrigation system and adverse effects. Last, patients no longer using a Navina System were asked about the reason for cessation of treatment.

**Statistical Analyses**

Statistical analyses were conducted with SPSS for Windows, version 26 (SPSS, Inc., Chicago, IL). Our sample included all patients listed by our nurse practitioner to have ever been scheduled to start TAI with a Navina system in our center, and patients already using Navina whom were followed in clinic. Because of our small patient sample we assumed data were not normally distributed. Therefore, data are presented using medians and interquartile ranges. Some participants did not complete all questionnaires, these missing data were excluded from analyses. Differences between groups were either tested with Fisher’s Exact test, Mann-Whitney U test, McNemar’s test, or Wilcoxon Signed Rank
test as appropriate. Data-analysis was performed following a modified intention-to-treat principle, including all children of whom data was available, regardless of their TAI use. A P value of <0.05 was considered statistically significant.

The study protocol was reviewed by the local Medical Ethical Committee, which concluded that the Medical Research Involving Human Subjects Act (WMO) did not apply (W21_240#21.267). The study was conducted as per ISO 14155 requirements.

**Figure, Supplemental Digital Content 3: Patient flow chart**

![Patient flow chart](image-url)
### Table, Supplemental Digital Content 4: Health-related quality of life

|                        | Child report (functional) | Child report (organic) | Parent report (functional) | Parent report (organic) |
|------------------------|---------------------------|------------------------|---------------------------|------------------------|
| **PedsQL, total n**    | 20                        | 6                      | 17                        | 6                      |
| Physical functioning, median (IQR) | 88 (70-94) | 44 (31-88) | 88 (59-97) | 58 (28-81) |
| Emotional functioning, median (IQR) | 75 (58-85) | 60 (50-90) | 75 (55-85) | 63 (50-90) |
| Social functioning, median (IQR) | 90 (65-93) | 75 (65-80) | 70 (50-80) | 70 (60-75) |
| School functioning, median (IQR) | 68 (55-75) | 58 (50-60) | 60 (60-70) | 58 (50-65) |
| Total mean score, median (IQR) | 79 (64-86) | 57 (51-72) | 73 (67-84) | 60 (51-68) |

| **PedsQL – GI symptom scale, total n** | 19 | 6 | 17 | 6 |
| Constipation, median (IQR) | 68 (54-84) | 71 (62-87) | 79 (58-88) | 71 (28-82) |
| Total mean score, median (IQR) | 74 (61-87) | 78 (74-86) | 81 (67-89) | 79 (77-84) |

### Table, Supplemental Digital Content 5: Adverse reactions by catheter type and other adverse events

|                        | Catheter type | Never | Rarely | Sometimes | Often | Always |
|------------------------|---------------|-------|--------|-----------|-------|--------|
| **Pain during catheter insertion** | Regular | 3 (33%) | 1 (11%) | 3 (33%) | 2 (22%) | 0 (0%) |
|                        | Small | 5 (62.5%) | 1 (12.5%) | 2 (25%) | 0 (0%) | 0 (0%) |
|                        | Cone | 0 (0%) | 0 (0%) | 1 (100%) | 0 (0%) | 0 (0%) |
| **Catheter does not stay in place** | Regular | 4 (44%) | 4 (44%) | 0 (0%) | 1 (11%) | 0 (0%) |
|                        | Small | 5 (62.5%) | 2 (22%) | 1 (12.5%) | 0 (0%) | 0 (0%) |
|                        | Cone | 0 (0%) | 0 (0%) | 1 (100%) | 0 (0%) | 0 (0%) |
| **Abdominal pain during TAI** | Regular | 1 (11%) | 2 (22%) | 4 (44%) | 2 (22%) | 0 (0%) |
|                        | Small | 1 (12.5%) | 1 (12.5%) | 3 (37.5%) | 3 (37.5%) | 0 (0%) |
|                        | Cone | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (100%) |
| **Fluid leaks during infusion of the fluid** | Regular | 3 (33%) | 1 (11%) | 3 (33%) | 2 (22%) | 0 (0%) |
|                        | Small | 2 (25%) | 3 (37.5%) | 2 (25%) | 1 (12.5%) | 0 (0%) |
|                        | Cone | 1 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

**Other responses:**
- Incorrect error messages (n=1, Navina Smart-user);
- An error message whilst inflating the balloon which can be prevented by inflating the balloon before insertion (n=1, Navina Smart-user);
- Bursting of the balloon and repetitive expulsion of the balloon which results in repeating the TAI procedure (n=1, Navina Smart-user).