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## BACKGROUND

Chronic inflammatory bowel diseases (IBD) are on the rise worldwide. About 20% of cases are diagnosed in the first two decades of life [1]. For children and adolescents, IBD is a threat to their physical, psychosocial and professional development. Previous studies showed that delivery of care is not optimal in international studies, further increasing the risk of long term complications and impairment [2]. In 2004, the Association for Pediatric Gastroenterology and Nutrition (GPGE e.V., Gesellschaft für pädiatrische Gastroenterologie und Ernährung) started the patient registry CEDATA-GPGE®. Since 2011, the registry can be used through a web-based online portal. The CED-KQN project, funded by the G-BA Innovation Fund, aims to use new technologies and innovative approaches to improve the delivery of care to children and adolescents with IBD. The aim of the CLARA study is to investigate the influence of participation in the patient registry due to specific feedback in CEDATA-GPGE® on the quality of health care for patients with IBD, measured by health outcomes and number of care deficits that can be observed.

## RESEARCH QUESTION

Can register-based feedback to health care practitioner reduce supply gaps in the treatment of children and adolescents with IBD?

**Primary endpoint:**  
 Number of care deficits after 12 months  
 (1 care deficit = 1 given register-based feedback)

**Secondary endpoints:**  
 Steroid-free remission for one year, inflammatory activity, therapeutic escalation, complications, physical development, quality of life, nutritional deficiencies, time between signs of inflammatory activity, treatment recommendation and treatment adjustment

## STUDY DESIGN

The cluster-randomized study is two-armed, randomized and controlled. Pediatric gastroenterological centers that are not currently reporting to the registry may participate in the study. The centers are randomized into an intervention group and a control group.

The study includes patients with a newly diagnosed IBD who have not yet reached the age of 18. The inclusion of patients was between 03.01.2019 and 28.02.2021. The follow-up period for each patient is 12 months, starting with initial reporting.

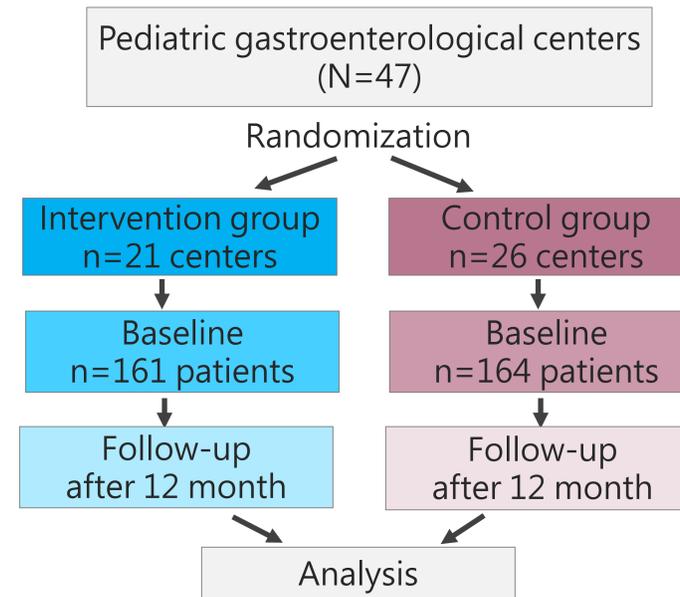


Fig. 1 : CONSORT flowchart for the cluster randomized study in the CED-KQN project

## INTERVENTION

The participating centers of the **intervention group** document all the treatment parameters of their patients in the patient register CEDATA-GPGE®. After the documentation, the centers receive individual feedback on the diagnostic and treatment data entered. The feedback relates to:

- Completeness of data in terms of endpoints to be investigated
- Feedback on treatment, e. g. on prescribed doses in drug therapy (see Figure 2).

Fig. 2: Examples of feedback in CEDATA-GPGE®

## STUDY PROCESS

### Intervention group

After initial reporting (baseline), patients are invited for follow-up visit after 6 and 12 months. The diagnostic and treatment data of the follow-up appointment are obtained. Diagnostic and treatment data for both groups are evaluated and compared at the end of the last observation period (12-month follow-up).

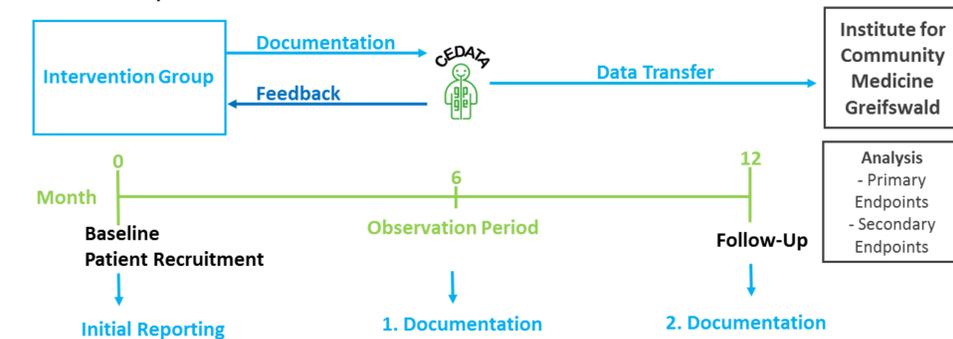


Fig. 3: Study progress in the intervention group

### Control group

Control group practitioners continue their usual documentation based on patient records etc. and do not receive any feedback. After the observation period, the diagnostic and treatment data are collected retrospectively from the patient records and transferred to the CEDATA-GPGE® register for data analysis.

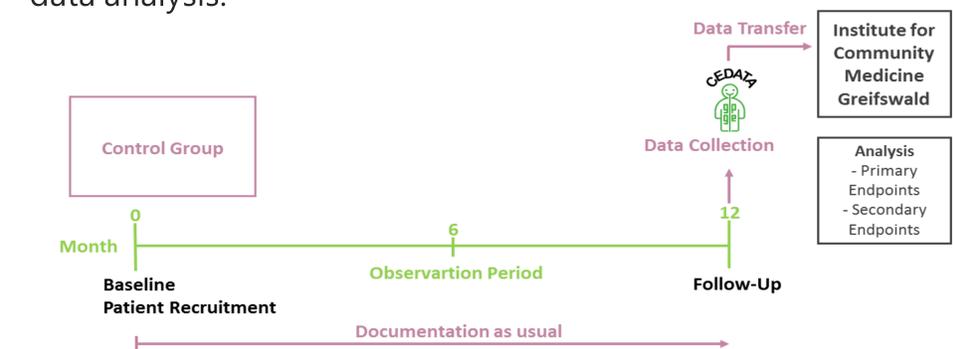


Fig. 4: Study progress in the control group

## SUMMARY

The CLARA-study is part of the CED-KQN project, funded by the German Innovation Fund. The purpose of this project is to improve health care based on the patient register (CEDATA-GPGE®) by using new technologies and innovative approaches, we are confident to present results in 2022

The authors of this poster have no conflict of interest with respect to this study.