

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Evaluation of the individual targeted promotion in day-care centers in Mecklenburg-Western Pomerania

Trial Acronym

GIF M-V

URL of the trial

<http://www2.medizin.uni-greifswald.de/icm/index.php?id=584>

Brief Summary in Lay Language

Due to the high prevalence of developmental risks in the areas of fine motor skills, gross motor skills, language and social development, the high utilization and the positive influence of preventive setting approaches, the day-care center is a relevant setting to prevent developmental risks in early years.

For these reasons, in 2010 the federal state law for children´s day care and preschools in Mecklenburg-Western Pomerania (KiföG M-V) was amended. Since then, certain day-care centers predominantly in social hotspots can receive additional financial resources. The additional funds shall be used for the targeted individual support of children with developmental risks. The finances can be used either for personal costs and/ or materials. To identify the children at risk, the day-care centers have to document each child´s development by using a standardized, objective and valid screening instrument. The "Dortmund Developmental Screening for Preschools" (DESK 3-6) is used for the age-adjusted early detection of children with developmental risks in the area of fine motor skills, gross motor skills, language and cognition as well as social development. The aim of the state law is to reduce social inequalities in child development in order to increase the equal opportunity of all children at the start of school.

The evaluation of the KiföG M-V answers the following questions:

- What is the incidence and prevalence of developmental risks in the merntioned areas?**
- Can significant improvements in child skills be identified over the years?**
- What do the day-care centers do to prevent developmental risks?**
- Which determinants influence the child's development (for example, gender, age, regular day-care center attendance, amount of additional weekly working hours)?**
- Can the results of the school entry examination be predicted with the DESK 3-6?**
- Are day-care centers able to balance detected developmental risks in the subsequent years?**

Brief Summary in Scientific Language

The evaluation of the federal state law for children´s day-care and preschools Mecklenburg-Western Pomerania is designed as a dynamic cohort study including

155 day-care centers [01.07.2018]. The evaluation uses a validated screening instrument, which longitudinally assesses the dimensions fine motor, gross motor, speech and cognition and the social development conducting an annual measurement waves. The longitudinally assessed data are matched on a child-specific level using the ID Management solution E-PIX (Enterprise Identifier Cross Referencing) of the Independent Trusted Third Party of the Universitymedicine Greifswald, which allows for unambiguous pseudonymized participant management.

Data from questionnaire-based surveys of the managing staff of the DESK-day-care centers are another part of the evaluation. Further analyses are carried out based on data from the school entry examination from Mecklenburg-Western Pomerania.

Database for analyses [01.01.2018]: ~24.500 children and every year ~ 14.000 data from the school entry examination

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00015134**
- Date of Registration in DRKS: **2018/10/29**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **BB109/11 , Ethikkommission an der Medizinischen Fakultät der Ernst-Moritz-Arndt-Universität Greifswald**

Secondary IDs

Health condition or Problem studied

- Free text: **developmental risks in the areas fine and gross motor, language and cognition as well as the social development of children in day-care centers, developmental risks of school starters (school entry examination)**
- ICD10: **F80 - Specific developmental disorders of speech and language**
- ICD10: **F81 - Specific developmental disorders of scholastic skills**
- ICD10: **F82 - Specific developmental disorder of motor function**
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ICD10: **F83 - Mixed specific developmental disorders**

- ICD10: **F84 - Pervasive developmental disorders**
- ICD10: **F88 - Other disorders of psychological development**
- ICD10: **F89 - Unspecified disorder of psychological development**

Interventions/Observational Groups

- Arm 1: **All day-care centers involved exceed a certain proportion of parents receiving state welfare benefits to subsidize their contribution payments above average and receive additional financial funds for the targeted individual promotion of developmental risks according to the federal state law of children's day-care and preschools Mecklenburg-Western Pomerania. The day-care institution can decide upon their use of the funds, e.g. for additional personnel and/ or material. To identify the children with developmental risks, a screening is carried out once a year for all 3- to 6-year-olds. All day-care centers receive a standardized training by the project team (in-house) prior to the screening (Dortmund Development Screening for preschools, DESK). The screening is carried out independently by the familiar day-care teachers (period: May - November of each year). If parental consent is given, the data are transferred to the project team.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Prevention**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary Outcome is the decrease of the proportion of schoolstarters at risk over time (school entry examination).

Instruments:

school entry examination: social-paediatric screening of developmental status for school entry (SOPESS)

Secondary Outcome

Secondary Outcome ist the decrease of the incidence and prevalence of children at risk in the day-care centers involved

instruments:

**child's skills: Dortmund Developmental Screening for Preschools (DESK 3-6 R);
questionnaire for administration staff of the day-care centers: developed in the project**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- **other Kindertageseinrichtungen, Mecklenburg-Vorpommern**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/11/01**
- Target Sample Size: **24500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **3 Years**
- Maximum Age: **6 Years**

Additional Inclusion Criteria

day-care centers with a proportion of parents receiving state welfare benefits to subsidize their contribution payments above average, day-care centers with additional financial support according to the federal state law of children's day-care and preschools Mecklenburg-Western Pomerania, preschoolers aged 3 to 6 years

Exclusion criteria

day-care centers without additional financial support according to the federal

state law of children´s day-care and preschools Mecklenburg-Western Pomerania

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.