

Trial Description

Title

Follow-up Assessment of the Midterm Efficacy of the Home Visiting Program Pro Kind Based on a Randomized Controlled Trial

Trial Acronym

[---]*

URL of the trial

<https://www.gesundheitsforschung-bmbf.de/de/prokind-5016.php>

Brief Summary in Lay Language

The present study is a follow-up assessment of the Pro Kind home visiting program for disadvantaged first-time mothers implemented in three German federal states from 2006 until 2012. The follow-up study aims to investigate the effects of the intervention on maternal and child health outcomes, maternal socio-economic development and cognitive and socio-emotional child development when the child starts primary school. To investigate the program effects, the study uses development assessments, telephone interviews with the mother as well as questionnaires for the teachers and administrative data.

Update: As part of the update of the study registration, the primary and secondary endpoints were systematized more strongly on the basis of the underlying effect hypotheses. At the time of the update, no digitized and aggregated study data is available.

Brief Summary in Scientific Language

The home visiting program Pro Kind was implemented in three German federal states from 2006 until 2012. Primary project aims were prevention of maternal and child health problems, amelioration of maternal health behavior during pregnancy, strengthening of parental competencies to prevent child abuse and neglect, and the improvement of children`s cognitive, psychomotor, language and social-emotional development. The program effects were evaluated longitudinally in a trial with randomized control group design (RCT) with N=755 high-risk primiparae enrolled. Large data sets to answer interdisciplinary research questions (at the interface of developmental psychopathology, economy, and criminology) were collected in one pre- and four posttests and periodical telephone interviews until the child`s second birthday. Results show that the program impact is concentrated on various maternal behavior outcomes like parenting skills and fertility decisions, with smaller impact on children`s cognitive development measured by Bayley Scales of Infant Development II (BSID II). Since it is well known from the international literature, short term effects of home visitation are small, but early intervention unfolds its positive effects in the longer run.

The purpose of the present proposal is to continue our panel with one follow-up assessment between child`s age six and seven. We expect positive effects on familial health and life circumstances, parental skills, as well as children`s school



readiness and their cognitive and socio-emotional developmental outcomes. Furthermore, the fiscal consequences of these effects are considered.

Organizational Data

- DRKS-ID: **DRKS00007554**
- Date of Registration in DRKS: **2015/06/11**
- 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.: **SK 122014 , Ethik-Kommission DGPsychologie**

Secondary IDs

Health condition or Problem studied

- Free text: **Mental stress and disruptions, family health, parental efficacy, school and social competencies of the children, cognitive and socio-emotional child development, aggression of the child, child abuse and neglect, physical aggression and violence against the child, Bullying and victimization of the child.**

Interventions/Observational Groups

- Arm 1: **The follow-up evaluation does not contain any intervention. In the age of 6 to 7 one combined interview with the mother and a developmental test with the child are conducted. Additionally, one telephone interview takes place, the child's teacher is interviewed and administrative data from the Federal Employment Agency and from health insurance companies are requested.**

In the first Pro Kind project stage, arm 1 had access to the regular German welfare state services. They received monetary incentives for participating in the study, feedback on child development and an address list with support services. Additionally women in the treatment group received the Pro Kind home visits.

- Arm 2: **Arm 2 does not receive any intervention in the follow-up evaluation. In the age of 6 to 7 one combined interview with the mother and a developmental test with the child are conducted. Additionally, one telephone interview takes place, the child's teacher is interviewed and administrative data from the Federal Employment Agency and from health insurance companies are requested.**

In the first project stage arm 2 had access to the regular German welfare state services. They received monetary incentives for participating in the study, feedback on child development and an address list with support services.

Arm 2: Arm 2 does not receive any intervention in the follow-up evaluation. In the age of 6 to 7 one combined interview with the mother and a developmental test with the child are conducted. Additionally, one telephone interview takes place, the child's teacher is interviewed and administrative data from the Federal Employment Agency and from health insurance companies are requested.

In the first project stage arm 2 had access to the regular German welfare state services. They received monetary incentives for participating in the study, feedback on child development and an address list with support services.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **assessor**
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

In the age of 6 to 7 one combined interview with the mother and a developmental test with the child are conducted. Additionally, one telephone interview takes place, the child's teacher is interviewed and administrative data from the Federal Employment Agency and from health insurance companies are requested.

The home visiting program has a positive effect on the child's cognitive development and school performance.

-->School performance: Basic diagnostics of Specific Developmental Disorders of Speech and Language at primary school age (BUEGA)

-->Cognitive development: BUEGA

-->Specific developmental disorders: BUEGA

The home visits have a positive effect on the child's mental health.

-->The child's behavioral problems and emotional disorders: Child Behavior Checklist (CBCL 6/18 R]), German version

The home visits have a positive effect on the child's life satisfaction.

-->General Satisfaction with life: Inventory scale to measure the life quality of children and youths (ILK)

The home visits result in improved parenting skills (less inappropriate parenting behavior)

-->Dysfunctional parenting: Parenting Scale (PS), German version: target-group-specific adaptation by the authors

-->Non-violent disciplining: Conflict Tactic Scale Child Report (CTS-CR), interview of the children with picture cards. German version: translation by the AMIS group / Conflict Tactic Scale Parent Child (CTS-PC), German version: target-group-specific adaptation by the authors

The home visits reduce or prevent child abuse and the frequency of physical

violence.

-->“Minor” aggression: CTS-CR and CTS-PC

-->“Minor” physical violence: CTS-CR and CTS-PC

-->Child abuse: CTS-PC

The home visits reduce or prevent child Neglect.

-->Physical neglect: Scale of the Multidimensional Neglectful Behavior Scale-Child Report (MNBS), interview of the children with picture cards. German version: translation by the AMIS group.

-->Emotional neglect: MNBS

-->Cognitive neglect: MNBS

-->Supervisory neglect: MNBS

The home visits influence the mother’s mental health

-->Mental stress:Depression-Anxiety-Stress Scale (DASS), German version: target-group-specific adaptation by the authors

Secondary Outcome

The home visits have a positive effect on the child’s mental health.

-->Attention deficit hyperactivity disorder and social behavior disorders (suspected diagnosis): Module from the diagnostic interview of mental disorders in children and youths (Kinder-DIPS)

-->Anxiety disorders (suspected diagnosis): Kinder-DIPS

-->Affective disorders (suspected diagnosis): Kinder-DIPS

The home visits have a positive effect on the child’s socio-emotional development.

-->The child’s social skills: Social Skills Improvement System (SSIS), German version: author’s translation

-->Aggression: Questionnaire regarding children’s aggressive behavior (FAVK)

-->Psychopathy: Inventory of Callous-Unemotional Traits (ICU), German version by Essau

The home visits influence the child’s preferences (risk behavior, pro-social behavior and time preference).

-->Pro-social behavior: Game for interpersonal allocation decisions

-->Risk behavior: Investment decisions in a lottery

-->Time preference: Game for temporary allocation decisions

The home visits have a positive effect on the mother’s perceived social support.

-->Perceived social support:Questionnaire regarding social support (FSOZU-K6)

The home visits result in more stable partnerships with less frequent partner change, greater satisfaction with the partnership and less domestic violence in the partnership

-->Stability of partnership: Developed by the authors

-->Partnership satisfaction: Short form of the Partnership Questionnaire (PFB-K)

Psychological aggression: Conflict Tactics Scales (CTS2); German version: target-group-specific adaptation by the authors [forward-backward]

-->Psychological aggression: CTS2

-->Physical violence: CTS2

-->Sexual assault:CTS2

-->Injuries due to assaults by the partner: CTS2

The home visits improve the parental self-efficacy expectations regarding the parenting tasks.

-->Parenting self-efficacy: Parenting Sense of Competence Scale (PSOC)), German

**The home visits increase the share of mothers in employment or education programs.**

--> **Acceptance of employment and Acceptance of training or educational offerings: The German Socio-Economic Panel (SOEP) and the Panel Arbeitsmarkt und Soziale Sicherung**

The home visits reduce the families' use of welfare payments (SGB II, SGB III and SGB VIII [Social Security Codes]).

--> **Welfare payments: Integrated Employment History provided by the Institute of Employment Research (IAB)**

--> **The home visits have a positive effect on the family's living situation.**

--> **Family Situation: The Home Observation for Measurement of the Environment (HOME forward-backward translation by the authors)**

The home visits influence the timing or frequency of a renewed pregnancy and births

--> **Renewed pregnancy / Renewed desire to have children / Abortions / Births: Questionnaire about intended and realized fertility. Integrated Employment History provided by the Institute of Employment Research (IAB)**

The home visits improve the mothers' physical health.

--> **Mother's physical health: 12-Item Short Form Survey (SF-12)**

The home visits increase the frequency of pediatric primary care use (e.g. screenings, vaccinations, child's oral health care and dentist visits).

--> **Frequency of pediatric primary care use: KiGGS questionnaire and doctor visits with ICD Z**

Home visits reduce the children's hospital visits (outpatient or inpatient) caused by accidents and injuries.

--> **Number of injuries: Hospital admission and doctor visits with ICD S and T**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Kriminologisches Forschungsinstitut Hannover (KFN), Bremen, Niedersachsen und Sachsen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/06/15**
- Target Sample Size: **755**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
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Gender: **Female**

Minimum Age: **no minimum age**

■ Maximum Age: **no maximum age**

Additional Inclusion Criteria

Participation in the first stage of the Pro Kind evaluation. Resident in Germany. (In the first program stage Pro Kind intervention registered only financially or socially disadvantaged first-time mothers during their 12th to 28th weeks of pregnancy. Financial disadvantage is defined as receipt of social welfare benefits, unemployment compensation, an income that is as low as social welfare benefits, and/or over-indebtedness. The considered social risk factors included, for example, low education, teenage pregnancy, social isolation, violent experiences, and health problems.)

Exclusion criteria

Insufficient knowledge of German language, without permanent residence permission.

Addresses

■ **Primary Sponsor**

**Kriminologisches Forschungsinstitut Hannover
Lützerodestraße 9
30161 Hannover
Germany**

Telephone: **0511 / 348 360**

Fax: **0511 / 348 36 10**

E-mail: **kfn at kfn.de**

URL: **http://www.kfn.de/home.htm**

■ **Contact for Scientific Queries**

**Kriminologisches Forschungsinstitut Hannover
Mr. Dr. Sören Kliem
Lützerodestraße 9
30161 Hannover
Germany**

Telephone: **0511 / 34836-37**

Fax: **[---]***

E-mail: **soeren.kliem at kfn.de**

URL: **[---]***

■



Contact for Public Queries

Kriminologisches Forschungsinstitut Hannover
Ms. Pädagogische Psychologin MSc Sabrina Lauenroth
Lützerodestraße 9
30161 Hannover
Germany

Telephone: **0511 / 34836 - 73**

Fax: [---]*

E-mail: **mona.bode at kfn.de**

URL: [---]*

■ Collaborator, Other Address

Institut für Arbeitsmarkt und Berufsforschung
Mr. Dr. Malte Sandner
Germany

Telephone: **+49 (911) 179 5809**

Fax: [---]*

E-mail: **sandner at iab.de**

URL: [---]*

■ Collaborator, Other Address

Universität Rostock
Ms. Prof. Dr. Tanja Jungmann
Germany

Telephone: **0381/4982672**

Fax: [---]*

E-mail: **tanja.jungmann(at)uni-rostock.de**

URL: [---]*

■ Collaborator, Other Address

Universitätsklinikum Leipzig, Kinder- und Jugendpsychiatrie
Mr. Prof. Dr. Kai von Klitzing
Germany

Telephone: **0341/9724010**

Fax: [---]*

E-mail: **Kai.vonKlitzing at uniklinik-leipzig.de**

URL: [---]*

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.)**

Bundesministerium für Bildung und Forschung Dienstsitz Bonn

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Research (BMBF), etc.)**

**Bundesministerium für Bildung und Forschung Dienstsitz Bonn
Heinemannstr. 2
53175 Bonn
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* 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.