

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

## Trial Description

### Title

**A prospective investigation of developmental trajectories of psychosocial adjustment in adolescents facing a chronic condition**

### Trial Acronym

**COACH**

### URL of the trial

<https://www.uni-pots-dam.de/de/beratungspsychologie/forschung/laufende-projekte;>  
<https://www.gesundheitsforschung-bmbf.de/de/coach-patientenzentrierte-interdisziplinare-gesundheitsversorgung-bei-chronisch-kranken-7261.php>

### Brief Summary in Lay Language

**Chronic diseases mean facing an additional challenge in life. Individuals with chronic diseases are at higher risk of psychological stress and reduced health-related quality of life. Especially during adolescence, youths are confronted with a range of developmental tasks, e.g. finding a partner, preparing for future family and work life, accepting the own body, which can strongly interfere with the demands of a chronic disease.**

**The study aims to understand which personal strengths, skills and resources help adolescents and emerging adults to cope with the challenges of a chronic disease (type 1 diabetes, juvenile idiopathic arthritis, cystic fibrosis).**

### Brief Summary in Scientific Language

**Based on resilience-in-illness models, we will examine resources and adaptive processes in adolescents with a chronic disease (type 1 diabetes, juvenile idiopathic arthritis, cystic fibrosis). These analyses might contribute to a lasting improvement of the treatment of this patient group. Therefore, we investigate the dynamic relationship between intrapersonal resilience factors (resiliency) and coping strategies in order to explain individual differences in psychosocial adjustment of adolescents with chronic conditions. The key question is whether resiliency and coping strategies play a significant role in psychosocial adjustment beyond the influence of general demographic and disease-related factors and as a consequence whether possible high-risk groups could be identified. A deeper understanding of adaptive, potentially modifiable processes within this sensitive developmental phase will help to develop novel, tailored interventions for positive adaptation in youths with chronic diseases. These strategies should not only support those at risk but also promote the maintenance of a successful adaptation.**

**Do you plan to share individual participant data with other researchers?****Yes****Description IPD sharing plan****The following documents will be provided:**

- **Study protocol**
- **Scale manual**

**Period:**

- **Fully anonymized data will be made available after a moratorium of five years.**

**Procedure:**

- **A reasonable request must be made.**

**Organizational Data**

- DRKS-ID: **DRKS00025125**
- Date of Registration in DRKS: **2021/05/17**
- 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.: **37/2018 , Universität Potsdam, Ethikkommission, Am Neuen Palais 10, Haus 9, 14469 Potsdam**

**Secondary IDs****Health condition or Problem studied**

- ICD10: **E10 - Type 1 diabetes mellitus**
- ICD10: **M08 - Juvenile arthritis**
- ICD10: **E84 - Cystic fibrosis**

**Interventions/Observational Groups**

- Arm 1: **Children and adolescents with chronic physical diseases (type 1 diabetes, juvenile idiopathic arthritis or cystic fibrosis), participate in an online questionnaire survey via SoSci-Survey at two measurement time points one year apart. Two groups are considered: Adolescents who were conspicuous in a screening for anxiety (GAD-7) or depression (PHQ-9) and those who were**

**inconspicuous (GAD7 and PHQ-9 below 7 points). The subjects are asked about the following aspects:**

**Sociodemographic and disease specific information**

- **Disease severity, age at disease diagnosis, etc.**

**Outcome: Health related quality of life and well-being (T1 and T2)**

- **Well-being (WHO-5)**
- **Health related quality of life (DCGM-37)**
- **Satisfaction with life (SWLS)**
- **General well-being (SAM)**

**Resources (T1 and T2)**

- **Resources (FRKJ 8-16)**
- **Self-control (SCS-K-D)**
- **Self-compassion (SCS-D Kurzversion)**
- **Social skills (FSK-KJ)**
- **Social support in coping with illness (BSSS)**
- **Body functionality (FAS)**

**Coping strategies (T1 and T2)**

- **Strategies (CODI)**
- **Problem solving (SSKJ 3-8)**
- **Cognitive emotion regulation (ERQ; CERQ)**
- **Posttraumatic growth (BFSC)**

**Psychopathology (T2)**

- **Depression (PHQ-8)**
- **Anxiety (GAD-7)**

**Developmental tasks and critical life events (T2)**

- **Developmental Tasks**
- **Critical Life Events**

**Psychological distress (T2)**

- **Perceived stress (PSS-4)**
- **Impact of Covid pandemic**

**Corona-specific Items**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Other**
- Purpose: **Prognosis**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

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Study Type Non-Interventional: **Observational study**

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Blinding: [---]\*

Who is blinded: [---]\*

Control: **Other**

Purpose: **Prognosis**

Assignment: **Parallel**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Health related quality of life (DCGM-37/DCGM-12)**

### Secondary Outcome

**Well-being (WHO-5), Satisfaction with life (SWLS), Depression (PHQ-9), Anxiety (GAD-7), Posttraumatic growth (BFSC)**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

- **other Die Rekrutierung erfolgt über Einrichtungen, die sich an den drei krankheitsbezogenen Patientenregister beteiligen (siehe Homepage der Beratungspsychologie, Uni Potsdam, für eine Übersicht der kooperierenden Einrichtungen)., [---]\***

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/03**
- Target Sample Size: **450**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **12 Years**
- Maximum Age: **21 Years**

## Additional Inclusion Criteria

**Recruitment conducted through institutions participating in the three disease-related patient registries (see homepage for overview of cooperating clinics).**

## Exclusion criteria

**none**

## 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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E-mail: [---]\*

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## Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]\*
- Reason, if Reason for Recruiting Stop "Other": [---]\*



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Date of Registration in Partner Registry or other Primary Registry: [---]\*

- Study Closing (LPLV): [---]\*
- Number of Participants in Germany after Recruiting complete: [---]\*
- Total Number of Participants (all Sites worldwide) after Recruiting complete: [---]\*

## 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.