

**Trial Description****Title**

**Questionnaire Survey on Insurants' Satisfaction with 'Gesundes Kinzigtal Integrated Care'**

**Trial Acronym**

**GeKiM**

**URL of the trial**

**[---]\***

**Brief Summary in Lay Language**

**In the Kinzigtal region - a region surrounding the valley of the river Kinzig in Southwest Germany - an integrated health care project has started in late 2005, attempting to overcome the traditionally fragmented German health care system within this region.**

**In general, the goal of integrated care systems is to improve the cooperation of health care providers within and between different health care sectors.**

**This study gathers data, by means of a standardized questionnaire (sent by normal mail), first of all on enrolled patients' satisfaction with (a) their respective doctor of confidence, and (b) with the integrated care system as a whole. For this sake a random sample of enrolled insurants is surveyed.**

**An amendment of the study was proposed to the ethics committee of the University of Freiburg on August 26, 2014. Accordingly, the study will be amended with respect to two aspects: (1) The study will be continued as a trend study, with the first follow-up taking place two years after the baseline survey. (2) The standardized questionnaire will additionally contain the following instrument in all follow-up surveys: PAM-13-D (German version of the "Patient Activation Measure"). The proposed amendment was considered sound in ethical respects (294/12\_140826; letter by the ethics committee as of September 03, 2014). (3) The follow-up survey will be sponsored by Gesundes Kinzigtal GmbH (address cf. below).**

**Brief Summary in Scientific Language**

**Standardized written questionnaire study in a sample of members of the 'Gesundes Kinzigtal Integrated Care' (GKIC)**

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

**[---]\***

**Description IPD sharing plan**

**[---]\***



## Organizational Data

- DRKS-ID: **DRKS00004283**
- Date of Registration in DRKS: **2012/09/06**
- 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.: **294/12 und 294/12\_140826 (Amendment) , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs

## Health condition or Problem studied

- Free text: **Primary target variables are items describing patients' satisfaction (a) with their respective doctors of confidence and (b) with the integrated care system as a whole. Furthermore, patients rate their individual health by a common Likert scale and with the aid of the EQ-5D questionnaire.**
- ICD10: [---]\* - [---]\*

## Interventions/Observational Groups

- Arm 1: **Observational study: a random sample of patients who have enrolled into 'Gesundes Kinzigtal Integrated Care' is surveyed every second year with the aid of standardized questionnaire.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Health care system**
- Assignment: **Single (group)**
- Phase: **N/A**
-



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Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

### Primary Outcome

**Primary outcomes are surveyed every two years: willingness to recommend IVGK to friends or relatives, willingness to re-entry in to IVGK (both 4-point Likert scales), health-related support in the IVGK system (5-point Likert scale), change of one's own health behaviour (3-point Likert scale), growth of one's own health-related knowledge (3-point Likert scale), satisfaction with one's doctor of confidence (Weisse-Liste-Ärzte questionnaire), patient activation (PAM-13-D).**

### Secondary Outcome

**Every two years: Health-related quality of life (EQ-5D).**

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/10/01**
- Target Sample Size: **900**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**at least 18 years in age; registered member of the care model 'Integrierte Versorgung Gesundes Kinzigtal'**

### Exclusion criteria

**younger than 18years; not registered in the care model**

### Addresses

#### ■ Primary Sponsor

**Abt. Med.Psychologie&Med. Soziologie, Medizinische Fakultät der Universität  
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URL: **http://www.medsoz.uni-freiburg.de**

#### ■ Contact for Scientific Queries

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#### ■ Contact for Public Queries

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Mr. Dr. Achim Siegel**



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## Sources of Monetary or Material Support

### ■ Institutional budget, no external funding (budget of sponsor/PI)

**Universität Freiburg, Medizinische Fakultät, Abteilung Medizinische Psychologie und Medizinische Soziologie**

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### ■ Commercial (pharmaceutical industry, medical engineering industry, etc.)

**Gesundes Kinzigtal GmbH**

**Ms. Dr. Monika Roth**

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**77716 Haslach**

**Germany**

Telephone: **+49 7832 974890**

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

E-mail: **info at gesundes-kinzigtal.de**

URL: **http://www.gesundes-kinzigtal.de/**

## Status

### ■ Recruitment Status: **Recruiting ongoing**

### ■ Study Closing (LPLV): **[---]\***

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## **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.*