### 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)

### 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
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
- 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 into 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 18 years; not registered in the care model
younger than 18 years; not registered in the care model

Addresses

Primary Sponsor

Mr. Dr. Ulrich Stoessel
Hebelstr. 29
79104 Freiburg
Germany

Telephone: +49(0)761/2035520
Fax: +49(0)761/2035516
E-mail: ulrich.stoessel at medsoz.uni-freiburg.de
URL: http://www.medsoz.uni-freiburg.de

Contact for Scientific Queries

Universitätsklinikum Freiburg, Lehrbereich Allgemeinmedizin
Mr. Dr. Achim Siegel
Elsässer Str. 2m, Haus 1A, DG
79110 Freiburg
Germany

Telephone: +49(0)761/27072970
Fax: +49(0)761/27072970
E-mail: achim.siegel at uniklinik-freiburg.de
URL: http://www.uniklinik-freiburg.de/studium/studieren-in-freiburg/lehrbereich-allgemeinmedizin.html

Contact for Public Queries

Universitätsklinikum Freiburg, Lehrbereich Allgemeinmedizin
Mr. Dr. Achim Siegel
Elsässer Str. 2m, Haus 1A, DG
79110 Freiburg
Germany

Telephone: +49 761 270 72970
Fax: +49 761 270 72970
E-mail: achim.siegel at uniklinik-freiburg.de
URL: http://www.uniklinik-freiburg.de/studium/studieren-in-freiburg/lehrbereich-allgemeinmedizin.html

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
Mr. Dr. Ulrich Stössel
Hebelstr. 29
79104 Freiburg
Germany

Telephone: +49 761 203-5520
Fax: +49 761 203-5516
E-mail: ulrich.stoessel at medsoz.uni-freiburg.de
URL: http://www.medsoz.uni-freiburg.de

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

Gesundes Kinzigtal GmbH
Ms. Dr. Monika Roth
Strickerweg 3d
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): [---]*

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.