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

Trial Description

Title

Communication skills training about clinical trials. A communication training for Oncologist

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

When oncologists disclose information about randomized clinical trials (RCT), they have to address requirements of high research standard and respect patients' rights. This is one of the most difficult communication tasks and physicians lack adequate training. Only few Communication Skills Trainings (CST) concerning this topic have been developed. Results show the need for further improvement: focusing on individual needs of participants and evaluation in a randomized design.

We developed an individualized CST, focusing on individual learning goals derived from video-assessment, and integrated a coaching after the workshop. For evaluation, 40 physicians were randomly assigned to training or waiting control group. Training success was evaluated by blinded rater using a specific checklist to evaluate video-recorded standardized consultations with actor-patients (1). The physicians' feeling of competence in general (2), after each consultation (3) and the satisfaction of actor-patients (4) were assessed using questionnaires.

Brief Summary in Scientific Language

When oncologists disclose information about randomized clinical trials (RCT), they have to address requirements of high research standard and respect patients' rights. This is one of the most difficult communication tasks and physicians lack adequate training. Only few Communication Skills Trainings (CST) concerning this topic have been developed. Results show the need for further improvement: focusing on individual needs of participants and evaluation in a randomized design.

Methods:
We developed an individualized CST, focusing on individual learning goals derived from video-assessment, and integrated a coaching after the workshop. For evaluation, 40 physicians were randomly assigned to training or waiting control

group. Training success was evaluated by blinded rater using a specific checklist to evaluate video-recorded standardized consultations with actor-patients (1). The physicians' feeling of competence in general (2), after each consultation (3) and the satisfaction of actor-patients (4) were assessed using questionnaires.

Expected Results:
The training will improve the communication skills of the participating medical doctors.

Organizational Data

- DRKS-ID: **DRKS00000492**
- Date of Registration in DRKS: **2010/07/22**
- Date of Registration in Partner Registry or other Primary Registry: **2008/03/27**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **180/06 , Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

- Partner Registry-ID: **UKF001580 (Register klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

Interventions/Observational Groups

- Arm 1: **The 17-hour long training combines a video-assessment, communication skills training and coaching. In the video-assessment individual learning goals are derived. These are used in the workshop and practised in in role play with actor-patients. In the Coaching there is a focus of how the individual learning goals are implemented in daily practise.**
- Arm 2: **The waiting-control group does not receive no training first. Later they participate on the intervention.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
-

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **Single blind**

- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **[---]***
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Improvment of key information about clinical trials, Evaluation of video-recorded consultations, evaluated by blinded rater with a checklist

Secondary Outcome

1.) Feeling of competence of physicians; questionaire at t0, t1, t2
2.) Understanding of actor patients; questionaire at t0, t1, t2
3.) Understanding of real patients, qualitative study

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/08/30**
- Target Sample Size: **40**
- 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

physicians in the field of oncology and RCTs

Exclusion criteria

physicians from other medical disciplines

Addresses

- **Primary Sponsor**

  Universitätsklinikum Freiburg
  Abt. Psychosomatische Medizin und Psychotherapie
  Mr. Alexander Wünsch
  Hauptstr. 8
  79104 Freiburg
  Germany

  Telephone: **+49 761 270-6878**
  Fax: **+49 761 270-6885**
  E-mail: **alexander.wuensch at uniklinik-freiburg.de**
  URL: **http://www.uniklinik-freiburg.de/psychosomatik/live/index.html**
- **Contact for Scientific Queries**

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  Mr. Alexander Wünsch
  Hauptstr. 8
  79104 Freiburg
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Hauptstr. 8
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Fax: **+49 761 270-6885**
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URL: **http://www.uniklinik-freiburg.de/psychosomatik/live/index.html**

Sources of Monetary or Material Support

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

Roche Pharma AG
Postfach 1260
79630 Grenzach-Whylen
Germany

Telephone: **+ 49 7624 14-0**
Fax: **+ 49 7624 14-1019**
E-mail: **christine.bender at roche.com**
URL: **www.roche.de**

- **Private sponsorship (foundations, study societies, etc.)**

Deutsche Krebshilfe
German Cancer Aid
Buschstr. 32
53004 Bonn
Germany

Telephone: **+ 49 228 729900**
Fax: **+ 49 228 7299011**
E-mail: **deutsche at krebshilfe.de**
URL: **www.krebshilfe.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2010/05/31**

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.*