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Can a video based short training intervention increase the extent to which patients and their doctors cooperate in treatment decision making?

Submission date
06/05/2011

Recruitment status
No longer recruiting

Registration date
20/06/2011

Overall study status
Completed

Last Edited
23/01/2019

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The process of medical decision making is a central focus of research on communication in health care. Nowadays, shared decision making (SDM) is regarded as the best practice model for this communicative challenge. In an SDM communication, the doctor and the patient exchange their knowledge about the treatment options, the medical evidence about their pros and cons, and the personal preferences of both participants. This should lead to a common, 'shared' decision between doctor and patient. Despite over 20 years of SDM research, the appropriate way of assessing both the quality of a physician's – and a patient's – SDM performance and the outcome of their effort is still to be defined. The aim of this study is to find out whether a video-based short training intervention increases the extent to which patients and their doctors cooperate in treatment decision making.

Who can participate?
Doctors and their patients aged 18-75

What does the study involve?
Participating doctors are randomly allocated to undergo the training either straight away or after a waiting period. During the training the participating doctors each video-record four consultations with their patients. Between the four consultations each doctor receives video-based individual coaching sessions supported by a manual and a DVD to help them to improve their communication in terms of SDM. Doctors, patients and observers (watching the video tapes) complete questionnaires to assess the effects of the training.

What are the possible benefits and risks of participating?
This study should make it possible to assess SDM, to teach SDM, and to better understand the effect of SDM on patients.

Where is the study run from?
Kiel Cancer Centre (Tumorzentrum Kiel) (Germany)

When is the study starting and how long is it expected to run for?
June 2011 to April 2012

Who is funding the study?
Kiel Cancer Centre (Tumorzentrum Kiel) (Germany)

Who is the main contact?
Dr Friedemann Geiger

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Investigating a Training Supporting Shared Decision Making (ITS SDM)

Acronym
ITS SDM

Study objectives
1. To evaluate a new intervention's ability to improve the communication in terms of SDM.
2. To further validate a newly deduced coefficient expressing the degree to which a communication involved physician and patient in an evidence based decision making process as the gold standard for measuring SDM
3. To evaluate SDM regarding its effects on decisional conflict and internal processes of elaboration
4. To further validate the 24 items short version of the Qualities of Uncertainty in Chronic

Conditions (QUiCC24)
5. To yield data on the interrelatedness of different perspectives on communication

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Faculty Ethics Board of Christian Albrecht University of Kiel, 12/04/2011, ref: D424/11

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer, multiple sclerosis

Interventions
1. A training curriculum addressing the participating physicians and goals at enhancing their efforts to involve their patients in the decision making process
2. It has been developed based on the newest available scientific knowledge on evidence based patient information (EBPI) and SDM
3. Its didactic is inspired by training techniques from psychotherapy education
4. Participants of doktormit SDM trainings are stimulated in three different ways:
4.1 They get insight into the framework of reference of SDM including a list of skills and corresponding theory and background information
4.2 They get an observer training incorporating the framework into the individual cognitive structure and motivating to increased awareness regarding own communication skills
4.3. They get opportunity to practice SDM and to incorporate newly learned skills and receive face to face feedback referring to their own communication style
5. The training includes three educational components
5.1. The manual was developed to comprehensively explain background and idea of SDM as well each of a set of 15 SDM skills which represent an extension of the range of skills published by Elwyn [2005]. Within the manual examples are used to illustrate varying degrees of performance.
5.2. The training video: Based on videos recording decision making consultations in a broad variety of medical indications a training video was developed showing every skill in a good to excellent performance. Within the video the skills are verbally edited according to the same framework of 15 skills.
5.3. The face to face feedback: Trainees get structured feedback based on a assessment of the video document of an own consultation in terms of the same framework of reference.
6.The feedback session lasts a maximum of 15 minutes follows a guideline passing six separate steps:
6.1. Introduction via surveying subjective benefit of the previous training steps
6.2. Statement that feedback does not refer to communication performance in general, but just to our specific viewpoint. The trainer indicates, that there are a lot of other important aspects of communication, one could focus on. The present focus is the way, the physician involves the patient into the decision to be made.

6.2. Actualisation of the specific consultation. Reporting context or particular events. e.g. by presenting a sequence of the video. Noting subject of the decision and duration of the decision sequence
6.4. Feedback referring to observable skills: concrete and with video examples
6.5. Asking for own ideas regarding potential for improvement
6.6. Specifying areas of potential improvement, using concrete examples and as far as possible building up on existing competencies. Checking understanding, reassuring tolerable volume of input.
7. The training deliberately abandons to provide the trainees with a general judgment of their performance, or to reach completeness in the feedback of the communication skills
8. The feedback should not create overall associations within the context of the other consultations. The feedback aims at concreteness and traceability.
9. Intervention is applied to intervention group, accompanied by a waiting period in the control group
10. Afterwards, the control group gets the full intervention while the intervention group is heading for a follow up assessment (6 months after randomisation) without any further interventions

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Coefficient SDM-MASS of the MAPPIN'SDM inventory
2. Components of the coefficient SDM-MASS of the MAPPIN'SDM inventory in comparison to:
2.1. OPTION (observing patient involvement) scale
2.2. SDM-Q
2.3. Dyadic coding scales (DCS)
3. Coefficient ELAB composed from the QUiCC24 questionnaire
4. As it is considered important that the trial does not negatively affect the practice process by burdening doctors and patients too much, measurement is limited to the necessary amount of instruments. Most of the measures were tested in previous studies to explore item properties and validity. In particular measures were selected to assess:
4.1. Both parties involvement in the decision making process using the SDM-MASS coefficient from the MAPPINSDM inventory, including video taping, questionnaires (15 items) from physician and patient
4.2. The patients perception of SDM using the SDM-Q (9 items)
4.3. To which extent involvement (in terms of SDM) impacts on the dyadic perception of decisional conflict using the Decisional Conflict scale (16 items to be administered by physicians and patients)
4.4. The pattern of uncertainty as it is represented in the patients cognitive system using the ELAB coefficient from the QUiCC24 (24 items to be administered by the patient before and after the consultation)

Key secondary outcome(s))
1. Item characteristics of QUiCC24 for validation purposes (Cronbach's alpha)
2. Item difficulty
3. Item total correlations coefficients between different foci of MAPPIN'SDM (doctor, patient, observer scales)

Completion date
01/04/2012

Eligibility

Key inclusion criteria
1. Doctor - patient dyads facing a decision (between treatment or diagnostic options) within a encounter
2. Aged 18-75, male or female

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
Less than two possible options to decide upon

Date of first enrolment
01/06/2011

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
Germany

Study participating centre
Klinik für Allgemeine Pädiatrie
Kiel
Germany
24105

Sponsor information

Organisation
Kiel Cancer Centre (Tumorzentrum Kiel) (Germany)

ROR
https://ror.org/04v76ef78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Kiel Cancer Centre (Tumorzentrum Kiel) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results of the efficacy of the doktormitSDM training module in supporting shared decision making.	01/12/2017	23/01/2019	Yes	No
Results article	results of training doctors briefly to involve their patients in making medical decisions.	01/12/2017	23/01/2019	Yes	No
Protocol article	protocol	26/10/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes