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Evaluation of the guideline evidence-based health information in combination with a training programme for providers of health information

Submission date
12/02/2019

Recruitment status
No longer recruiting

Registration date
07/03/2019

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Evidence-based health information (EBHI) is a prerequisite for informed and shared decision-making. The criteria for EBHI are comprehensively defined but the implementation into practice is still insufficient. The guideline evidence-based health information addresses providers of health information. Its goal is to improve the quality of health information material. The guideline was published on the website www.leitlinie-gesundheitsinformation.de in February 2017. Additionally, we explored the competencies of providers of health information and developed a 5-day training programme.

The aim of this study is to evaluate the implementation of the guideline evidence-based health information in combination with the training programme for the providers of health information. We assume that the guideline-based development of EBHI combined with a training programme will improve the quality of health information compared to the development without training and access to the guideline only.

Who can participate?
Providers of publicly available health information (e.g. health insurances, self-help associations or foundations, health portals, hospitals, rehabilitation clinics, nursing facilities and physicians) in the German-speaking area can participate. Providers are defined as institutions or working groups rather than individuals and may, therefore, comprise approximately one to ten individuals. 26 providers of health information will be enrolled.

What does the study involve?
We will conduct a randomised controlled trial to compare the intervention (guideline evidence-based health information & training programme) with usual care (guideline publicly available). Participating provider groups will be randomly allocated to either the intervention or the control group.

The training programme (which is free of charge) comprises two modules: an EbM-training module and a module for using the guideline. It is designed in a blended learning format where face-to-face and web-based learning activities alternate (three days of face-to-face training and two days of web-based training). The ebm training module aims to impart competences in searching for, selecting, critically appraising and extracting relevant literature according to the principles of evidence-based medicine (ebm).

Primary outcome is the extent to which the recommendations of the guideline are implemented. Therefore, each provider will develop one item of health information to a freely chosen subject within the study. The rating instrument, which is based on the guideline, is currently being validated. The instrument comprises quality criteria on relevant content and presentation formats. Additionally, we will perform a qualitative process evaluation.

What are the possible benefits and risks of participating?
We do not expect adverse events or other unintended effects of the intervention. However, providers have to release their employees from work for the training programme. They have to provide time and financial resources to develop the one item of health information in the study period, possibly with more effort in the intervention group in order to realize the guideline recommendations. In return, a final symposium with the presentation of the best information material will be scheduled after completion of the project. With their consent, the providers' logos will be published on the project website after completing the study. In addition, the health information produced in the study may be published on the website along with the results of the quality rating.

Where is the study run from?
Study centre is the Institute for Health and Nursing Science, Martin Luther University Halle-Wittenberg, Halle (Saale), Germany.

When is the study starting and how long is it expected to run for?
The study started in June 2018 and will run until June 2022

Who is funding the study?
The study is funded by the Innovationsfond zur Förderung von Versorgungsforschung (§ 92a Abs. 2 Satz 1 SGB V) under the project number: 01VSF17047. The funding institution will not interfere in any part of the study.

Who is the main contact?
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Study website
https://www.leitlinie-gesundheitsinformation.de/

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Feb 2019-Version 1

Study information

Scientific Title
Effect of a complex intervention comprising the guideline evidence-based health information and training programme on the quality of health information: study protocol of a randomised controlled trial

Acronym

IMLEGI

Study objectives
We expect the intervention, comprising the guideline evidence-based health information and a training programme addressing providers of health information, to improve the quality of health information in comparison to that achieved by access to the guideline only.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/05/2019, Ethics committee of the Martin Luther University Halle-Wittenberg (Magdeburger Straße 16, 06112 Halle (Saale), Germany; 0049 345 557 4476; ethik-kommission@uk-halle.de), ref: 2019-030

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet.

Health condition(s) or problem(s) studied
Evidence-based health information

Interventions
Participants in the intervention group receive the guideline evidence-based health information and an adjunctive training programme, which is intended to facilitate the appropriate use of the guideline.

The guideline defines the quality criteria of evidence-based health information (EBHI). It comprises general and ethical requirements regarding the development process, target group orientation and content of EBHI as well as 21 evidence-based recommendations assigned to the topics: presentation of frequencies, application of graphics, pictures and drawings, narratives, value clarification tools, formats, and involvement of the target groups.

The training programme (which is free of charge) is based on a problem-based instructional design that is learner-centred and empowers learners to integrate theory and practice, and apply knowledge and skills to develop EBHI to a defined health problem for special target

groups. Case-based learning links theory to practice through the application of knowledge about the cases and by using inquiry-based learning methods. We set up a case concerning smoking cessation.

The training programme is designed in a blended learning format. It comprises module 1 "EBM training" (two days of face-to-face training followed by one day of web-based training) and module 2 "Application of the guideline" (one day of web-based training followed by one day of face-to-face training). The ebm training module is divided into five sub-modules: introduction, treatment studies, evidence syntheses and guidelines, diagnostic studies and systematic literature search. For the web-based learning scenario, a learning management system (ILIAS) is used to provide web-based content.

Participants in the control group do not get access to the training programme or materials exceeding the guideline itself. They are offered the possibility of participating in the training programme after data collection is completed.

Concealed allocation of participating provider groups to either the intervention or the control group will be determined by randomisation using a computer-generated list with randomly permuted blocks of length 2, 4, 6 or 8. An independent external person will prepare sealed opaque envelopes. After baseline assessment of the respective provider group, researchers will open the sealed opaque envelope and reveal the centre's allocation on site.

Due to the nature of the intervention, blinding of the participating providers and researchers conducting the training programme is not possible. However, assessment of the primary endpoint and all analyses will be blinded towards group allocation.

There is no follow-up for individual participants.

However, data for the process evaluation will be assessed:
Feasibility and acceptance of the training programme will be assessed at the end of the training sessions using structured feedback and all statements will be documented. Critical health literacy will be assessed using the CHC test after the participants completed the training programme (intervention and control group).

After completing the health information, in the intervention group (theoretical sampling), semi-structured interviews will be conducted with single participants and persons in charge in order to explore the implementation barriers and facilitators.

Intervention Type
Other

Primary outcome measure
The quality of health information material produced by the participants using the instrument MAPP'INFO (MAPPin health INFOrmation quality). Quality is assessed after the production process has been finished and not later than 12 months. Quality is operationalised as the extent of compliance with the recommendations of the "Guideline for evidence-based health information".

Secondary outcome measures
Assessment is carried out along with the primary outcome by comparing the extent of compliance with the recommendations of the "Guideline for evidence-based health information":
1. Whether information about possible benefits is provided in an appropriate manner.

2. Whether information about possible harm is provided in an appropriate manner.
3. In the case of diagnostic problems: whether information about the reliability and safety of the test is provided in an appropriate manner.
4. The neutrality of the wording/language of the health information.
5. Whether the health information target group has been involved in the development process using appropriate methods.

Overall study start date
15/06/2018

Completion date
14/06/2022

Eligibility

Key inclusion criteria
1. Institutions or working groups (up to 10 members) responsible for the production and publishing of information material.
2. Have published any information in the last eighteen months.
3. At least a single information produced in the last three years has to fulfil the following criteria:
3.1. Has to inform a health-related decision.
3.2. Has to address patients or medical laypersons.
3.3. Has to discuss different options regarding one specified health problem.
3.4. Does not inform about a single option, procedure or healthcare system and it does not give general advice on health and wellbeing.

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
26 provider groups (13 in the intervention and 13 in the control group): 150 total individual participants

Total final enrolment
18

Key exclusion criteria
1. Members of the working groups on the guideline evidence-based health information or the GPGI are not eligible.
2. Produce exclusively (drug) fact(s) boxes
3. Offer exclusively counselling services such as medical online consulting websites, health-related blogs, forums or communities and (online) encyclopaedias.

Date of first enrolment

15/03/2019

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
Austria

Germany

Switzerland

Study participating centre
Institute for Health and Nursing Science, Martin Luther University Halle-Wittenberg, Halle (Saale), Germany
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Sponsor information

Organisation
German Aerospace Center (DLR)

Sponsor details
Deutsches Zentrum für Luft- und Raumfahrt e. V. (DLR)
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Sponsor type
Research organisation

Website
https://www.dlr.de/pt

ROR

https://ror.org/04bwf3e34

Funder(s)

Funder type
Research organisation

Funder Name
Innovationsfond zur Förderung von Versorgungsforschung (§ 92a Abs. 2 Satz 1 SGB V), Innovationsausschuss beim G-BA, Postfach 12 06 06, 10623 Berlin, Germany

Results and Publications

Publication and dissemination plan
The study center will coordinate the intra-study data sharing process. The data sets will be available for all the principal investigators.

All the results of the study (including negative ones) will be published in international and open-access journals and presented at meetings and congresses. According to the recommendations of the International Committee of Medical Journal Editors (ICMJE), only persons directly involved in the study will be designated as authors (41).
All the participants will receive an abbreviated version of the final report in language written for laypersons.

Intention to publish date
14/03/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. For this purpose, the European Open Science Cloud (EOSC), a collaborative tool for data sharing and reuse, was recently implemented and is to serve all researchers from all research domains (https://ec.europa.eu/research/openscience/index.cfm?pg=open-science-cloud).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/05/2020	27/05/2020	Yes	No
Other publications	qualitative study on the feasibility and acceptability of the programme	18/03/2020	09/07/2024	Yes	No