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Does an interactive summary of findings table improve users' understanding of and satisfaction with information about the benefits and harms of treatments?

Submission date
13/12/2015

Recruitment status
No longer recruiting

Registration date
08/01/2016

Overall study status
Completed

Last Edited
29/10/2018

Condition category
Other

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

Plain English summary of protocol

Background and study aims
We all need to make decisions about our health and treatments, and health and health research are often in the news. Information about treatments is sometimes confusing or hard to understand. To make it easier to understand for people making a decision about a treatment, we would like members of the public to test some different ways health research information can be presented. The DECIDE project is working to find ways to present information about treatments to all the people involved in making healthcare decisions, including patients and their families, healthcare managers, doctors, nurses and other health professionals. This is an important part of providing high quality healthcare.

Who can participate?
People aged over 18 who are on the SHARE online database of people in Scotland who are interested in participating in trials.

What does the study involve?
We have prepared some information on using the following treatments: antibiotics for middle ear infection; aspirin for primary prevention of cardiovascular disease; warfarin for atrial fibrillation. This information is based on the best research about treatment options for these health problems. We have prepared different ways of presenting this information. Participants are randomly allocated to be shown one of three ways of presenting information about one of these topics so that we can get their opinion on how helpful the information is. Completing the study takes around 15 minutes.

What are the possible benefits and risks of participating?
We aim to ask thousands of people to give their opinion, which will give a good idea of what works and what doesn't. Taking part in the study won't lead to an immediate benefit for

participants personally. However, it will help organisations that produce health information improve the way they do this. This may be help people in the future when making real decisions about treatments.

Where is the study run from?
1. Health Services Research Unit at the University of Aberdeen (UK)
2. Norwegian Knowledge Centre for the Health Services (Norway)

When is the study starting and how long is it expected to run for?
November 2014 to January 2016

Who is funding the study?
The European Union (Belgium)

Who is the main contact?
Prof. Shaun Treweek
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Study website
http://isof-trial.epistemonikos.org/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Does an interactive "Summary of Findings table", compared with standard evidence-based patient information and with a static Summary of Findings table, improve members of the public's understanding of and satisfaction with information about the benefits and harms of treatments?

Study objectives
1. An interactive Summary of Findings (iSoF) table compared to evidence-based patient information, and to static SoF tables will improve participants' understanding of, and satisfaction with, information about the benefits and harms of treatments when making a hypothetical decision
2. The initial iSoF table presentation will have an effect on understanding of, and satisfaction with, information about the benefits and harms of treatments when making a decision; and that participants will prefer interactive presentations, and certain initial presentations over the other presentations

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Aberdeen Life Sciences and Medicine College Research Ethics Board has prepared a checklist, which classes this work as very low risk and it therefore does not need formal review by their committee. The work will be conducted in accordance with the Ethical Review and Governance Framework of the University of Aberdeen.

Study design
Internet-based parallel randomized trial

Primary study design

Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
https://s3.amazonaws.com/isof_pdf/Participant+Information+sheet+2015+09+21.pdf

Health condition(s) or problem(s) studied
Understanding and satisfaction with evidence-based information about the harms and benefits of treatments

Interventions
Members of the public are recruited to participate in the trial via the internet. Participants will consent and complete the trial on-line., before being randomly allocated to one six groups. Each group will see a scenario for one of two baseline risk levels for one of three different topics, and involve making a hypothetical decision about whether or not to use a treatment. The three topics are antibiotics for acute otitis media, aspirin for primary prevention of coronary heart disease, and warfarin for atrial fibrillation. For each of these six groups we will then randomly allocate participants to see either evidence-based patient information, one of six initial presentations of an interactive SoF, or of a static SoF. Using an online questionnaire participants will be asked to make a hypothetical decision whether or not to use the treatment, questions about their understanding of the balance between the benefits and harms, the sizes of effects, the certainty of the evidence; and whether they are satisfied that they have been adequately informed about the benefits and harms of the treatment. Participants will then be shown the alternative presentations for the same scenario and risk level, and ask whether they prefer the standard patient information, an interactive SoF, a static SoF, a combination of standard patient information with an interactive SoF or with a static SoF, and the reasons for their preferences. They will also be asked which initial presentation of the iSoF table they prefer and the reasons for their preferences. There is no follow up for participants after they have completed the online trial questionnaire

Intervention Type
Other

Primary outcome measure
1. Participants' understanding of, and satisfaction with, information about the benefits and harms of treatments when making a decision is measured using a specially designed online questionnaire that they are given at the time of randomisation
2. Which presentations participants prefer is measured using a specially designed online questionnaire that they are given at the time of randomisation

Secondary outcome measures
1. The reasons for participants' preferences, their understanding of the balance of the benefits and harms, and their hypothetical decisions is measured using a specially designed online

questionnaire that they are given at the time of randomisation (baseline) and after the presentation
2. The primary outcomes in people who would like their doctor or somebody else to make a decision for them are excluded from the comparisons is measured using a specially designed online questionnaire that they are given at the time of randomisation (baseline) and after the presentation
3. Whether the primary outcomes vary across the six decision-making scenarios is measured using a specially designed online questionnaire that they are given at the time of randomisation (baseline) and after the presentation

Overall study start date
25/11/2014

Completion date
01/01/2016

Eligibility

Key inclusion criteria
1. Members of the public aged 18 or over
2. Registered on the SHARE online database of people in Scotland who are interested in participating in trials (www.registerforshare.org)

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3200

Key exclusion criteria
1. Familiar with GRADE SoF tables (assessed by asking participants)
2. Those who have previously participated in the trial
3. Those who have research training or experience equivalent to an MSc or PhD

Date of first enrolment
14/12/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Norway

Scotland

United Kingdom

Study participating centre
University of Aberdeen
Health Services Research Unit
3rd Floor, Health Sciences Building
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Study participating centre
Norwegian Knowledge Centre for the Health Services
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 29/10/2018:
Although 2290 people completed the online trial, the quantitative primary analysis was not possible. Unfortunately there was a fatal flaw in the web-based software that was not picked up during testing. This error meant that the iSoF did not work for some participants. We know this because some people commented on this. However, some participants appear to have completed the study even though the iSoF did not work for them and did not comment on this. Epistemonikos (the company that developed the software) cannot tell which participants had problems and which did not, so we can identify some, but not all of the participants for whom the iSoF did not work. This means that any quantitative analysis would be erroneous because it is not clear who actually received the iSoF intervention or not.

There are some qualitative data, which should still provide useful information. Changes in study staff circumstances have delayed the analysis of these data but the intention is that there will be a report describing these data.

Previous publication and dissemination plan:
The results will be published on the SHARE website. They will also be presented to guideline organisations and others through scientific documents, presentations and meetings. The results will be used to guide the way health information is presented in the future.

Intention to publish date
31/10/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request