# 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	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
		☐ Protocol		
<b>Registration date</b> 08/01/2016	Overall study status Completed	Statistical analysis plan		
		Results		
<b>Last Edited</b> 29/10/2018	<b>Condition category</b> Other	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 DECIDE iSoF@icloud.com

### Contact information

#### Type(s)

**Public** 

#### Contact name

**Prof Shaun Treweek** 

#### Contact details

Health Services Research Unit University of Aberdeen 3rd Floor, Health Sciences Building Foresterhill Aberdeen United Kingdom AB25 2ZD +44 775 614 4998 DECIDE iSoF@icloud.com

#### Type(s)

Scientific

#### Contact name

Dr Jenny Moberg

#### **ORCID ID**

https://orcid.org/0000-0003-4931-2438

#### Contact details

Norwegian Knowledge Centre for the Health Services Oslo Norway N-0130

#### Additional identifiers

Protocol serial number

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

#### Study type(s)

Other

#### 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(s)

- 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

#### Key secondary outcome(s))

- 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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

**United Kingdom** 

Scotland

Norway

# Study participating centre University of Aberdeen

Health Services Research Unit 3rd Floor, Health Sciences Building Foresterhill Aberdeen United Kingdom AB25 2ZD

#### Study participating centre Norwegian Knowledge Centre for the Health Services

Pilestredet Park 7 Oslo Norway N-0130

# Sponsor information

#### Organisation

Health Services Research Unit at the University of Aberdeen (UK)

#### **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**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

# Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes