

## [Protocol] Visual feedback of the individual's medical imaging results for changing health behaviours in clinical and non-clinical populations

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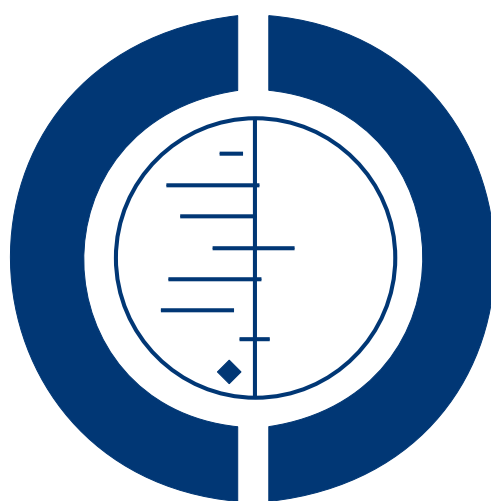
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# Visual feedback of the individual's medical imaging results for changing health behaviours in clinical and non-clinical populations (Protocol)

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[Intervention Protocol]

# Visual feedback of the individual's medical imaging results for changing health behaviours in clinical and non-clinical populations

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## ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

### Primary objective

To assess the extent to which presentation to the individual of images of their own body created during medical imaging procedures increases or decreases health behaviours such as:

1. dietary fat intake;
2. physical activity levels;
3. smoking;
4. alcohol use;
5. damaging exposure to sunlight or other sources of ultraviolet radiation.

This will be considered in comparison to the impact of communicating the same findings in a way which does not involve showing the person the source images derived from the imaging procedure (such as solely through oral feedback, or a written report).

### Secondary objective

A secondary objective is to determine the impact of this feedback on consumers':

1. understanding of the relevant condition and of the risk information they have been given;
2. perceived severity and risk of disease;
3. perceived control over the disease risk;
4. perceived effectiveness of the risk-reducing behaviour;
5. emotional response, including general anxiety and condition-specific worry.

## BACKGROUND

Achieving behaviour change is a major and perpetual challenge in medicine and public health. To this end, there is an ongoing interest in determining both the type of information and the means of delivery which can most powerfully motivate health behaviour change.

Providing individuals with their clinical biomarker results (results of tests which can reveal impaired bodily function, exposure to harmful substances, or susceptibility to disease) may be one motivation method. In a 2002 review, McClure reported that preliminary findings derived from eight trials suggested that such biomarker feedback can motivate health behaviour change (McClure 2002). The feedback of test results which are able to reveal actual bodily harm (for example, structural or functional bodily damage) attributable to a given behaviour may offer a particularly promising approach (Hirschl 2004), as the significance of such results may be immediately comprehensible. As medical imaging of the body (derived, for example, from ultrasound, X-ray or Magnetic Resonance Imaging (MRI) technologies) allows access to information which was previously unavailable and invisible, clinicians are able to produce assessments of existing bodily damage (or lack thereof) and to classify levels of future disease risk based on test results. Examples of applications include ultrasound and computed tomography to assess arterial calcification, ultrasound to assess liver damage and radiography to assess bone density relating to osteoporosis.

Imaging results typically require a degree of trained interpretation, and as such they require explanation in order for recipients to understand them. Such feedback to patients is often in the form of oral and/or written descriptions or classifications. The source images often remain privy to the medical staff and are not shown to the subject of the scan. It can also be the case that the medical images are delivered to the consumer but with little or no explanation from the medical practitioner.

This review examines the addition of the acquired images themselves to aid in the presentation of results and motivate behaviour change. The subject has received relatively little attention in the literature. In essence, interventions of this type consist of the individual being shown medical images of their body together with an explanation of what is portrayed and the implications of these results.

There are tentative indications that such visual feedback may add potency to risk communication. A recent Cochrane review of biomedical risk assessment as an aid in smoking cessation (Bize 2005) found that a study which utilised the feedback of ultrasound images showing the presence of arterial plaques (Bovet 2002) had the largest effect of any of the included interventions on smoking cessation behaviour. We are confident that there are now sufficient studies, including several in press, to make a review of the area viable.

Whilst diagnostic imaging is likely to be the principal focus of our review, medical imaging is also used in a non-diagnostic capacity, such as for educational or research purposes. Images obtained in this context may also be used in risk communication, but the possible behavioural effects have thus far been examined with healthy non-clinical populations. Examples include MRI to image body composition, and ultraviolet photography to image sun-related skin damage.

The use of diagnostic imaging is increasingly prevalent in clinical settings (Mitka 2005). Whilst visual feedback of source images to individuals is not generally incorporated within standard clinical procedures at present, it is sometimes provided dependent on context and case. The increasing availability of the technology offers a corresponding potential for increased use as a motivational aid, if research finds this to be effective.

The current review will collate the evidence concerning the behavioural impact of presenting images from personalised medical imaging in order to determine whether the feedback of imaging findings increases risk-reducing behaviour. We will examine the emotional and cognitive mediators and moderators of any behavioural change, and present recommendations for future research. We will also assess data on adverse events, such as anxiety (or other unanticipated psychological effects) caused by such interventions, or undesired behaviour change.

## OBJECTIVES

### Primary objective

To assess the extent to which presentation to the individual of images of their own body created during medical imaging procedures increases or decreases health behaviours such as:

1. dietary fat intake;
2. physical activity levels;
3. smoking;
4. alcohol use;
5. damaging exposure to sunlight or other sources of ultraviolet radiation.

This will be considered in comparison to the impact of communicating the same findings in a way which does not involve showing the person the source images derived from the imaging procedure (such as solely through oral feedback, or a written report).

### Secondary objective

A secondary objective is to determine the impact of this feedback on consumers':

1. understanding of the relevant condition and of the risk information they have been given;

2. perceived severity and risk of disease;
3. perceived control over the disease risk;
4. perceived effectiveness of the risk-reducing behaviour;
5. emotional response, including general anxiety and condition-specific worry.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised controlled trials and quasi-randomised trials are eligible for inclusion.

#### Types of participants

Clinical and non-clinical populations consisting of adult (18 years and over) non-pregnant individuals receiving medical imaging procedures assessing risk of disease or an existing condition (see below), for which personal risk may be reduced by modification of behaviour. We will also include studies of people making decisions on behalf of or assisting in the potential behaviour modification of the individual, such as family members or carers. Relevant conditions include (but are not limited to): cardiovascular disease, cancers, stroke, osteoporosis and diabetes.

#### Types of interventions

The sole or principal component of the intervention is visual feedback of an individual's medical imaging results. Visual feedback is defined as the individual being shown source images (still or moving images) of their body generated by the procedure in the course of the communication of their results. Typically we would expect this to consist of the individual being shown a medical image of their body (such as a scan image of arterial plaque) and being talked through the details of what the image portrays and the implications this has for their health and behaviour (in this example, outlining the role of health behaviour in determining their vascular health). We will exclude interventions which use library images or images of other people's scans only (rather than images of the individual themselves) as the focus of risk communication. We will include complex multiple-component interventions in which individual visual feedback is one of an array of interventions, on the condition that an effect-size can be ascertained for the individual visual feedback intervention component. We will present a separate table of studies which have multiple-component interventions including individual visual feedback, which are ineligible for inclusion.

For clarification, medical imaging is defined as the MeSH definition for diagnostic imaging, but applied without the consideration of diagnostic intent: "any visual display of structural or functional patterns of organs or tissues" (MeSH 2008). The specific

procedures which are encompassed under this definition, in line with MeSH organisation, include magnetic resonance imaging, tomography, radiography and ultrasonography.

Acceptable comparison groups are those that provide:

1. no risk information at all;
2. risk information derived from a non-medical imaging method (e.g. cholesterol test); or
3. personalised health-related risk information derived from medical imaging procedures but presented to the individual without visual feedback.

We will exclude studies which use imagined scenarios and risk information.

#### Types of outcome measures

Included trials must report a behavioural outcome or report the intention to engage in risk-reducing behaviour. All outcomes may be measured either objectively or subjectively.

#### Primary outcomes (behavioural endpoints)

Engagement in health-related behaviours that have the potential to modify the risk identified, such as:

- Dietary behaviour;
- Physical activity;
- Weight control;
- Smoking;
- Alcohol consumption;
- Attendance for screening;
- Sun protection behaviours;
- Adherence to medication;
- Use of drugs of abuse.

#### Secondary outcomes

Intention to engage in health-related behaviours that have the potential to modify the risk identified, such as:

- Dietary behaviour;
- Physical activity;
- Weight control;
- Smoking;
- Alcohol consumption;
- Attendance for screening;
- Sun protection behaviours;
- Adherence to medication;
- Use of drugs of abuse.

Cognitive and emotional mediators and moderators including:

- Understanding of the relevant condition and of the risk information they have been given;
- Perceived severity and risk of disease;
- Perceived control over the disease risk;
- Perceived effectiveness of the risk-reducing behaviour;
- Emotional response, including general anxiety and condition-specific worry;
- Acceptability of the intervention.

Physical/health status outcomes, such as:

- Blood pressure;
- Cholesterol level;
- Lung function;
- Weight;
- Level of atherosclerosis.

Costs associated with featured interventions.

#### **Adverse events**

Any adverse events that are reported in the included trials will be noted. These might include clinical levels of depression or anxiety.

### **Search methods for identification of studies**

#### **Electronic searches**

#### **Electronic searches**

We will search the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*),
- CINAHL (1982 to present),
- MEDLINE (1950 to present),
- EMBASE (1980 to present)
- PsycINFO (1985 to present).

The search strategies were developed to comprise searches both for keywords and medical subject headings under existing database organisational schemes. They aimed to identify articles reporting on randomised controlled trials that comprised both a disease risk assessment involving medical imaging feedback and a measure of the effect on behaviour. The strategy for MEDLINE (Ovid SP) is presented at [Appendix 1](#).

We will search the ProQuest Dissertations and Theses database for grey literature.

We will search databases in the metaRegister of Randomised Controlled Trials to identify ongoing studies. If applicable, we will present relevant ongoing studies in a table in the review.

#### **Searching other resources**

We will attempt to contact authors of all included studies (along with other key researchers in the field) to identify other studies, and to ascertain further details of methodology and data of included studies.

We will search reference lists of relevant studies and systematic reviews. We will not handsearch journals.

### **Data collection and analysis**

#### **Selection of studies**

Two review authors will pre-screen all search results (titles and abstracts) for possible inclusion, and those selected by either or both authors will be subject to full-text assessment. Two review authors will independently assess the selected articles for inclusion. Any discrepancies will be resolved by consensus, overseen by a third author acting as arbiter, with approval by one review author and the arbiter being sufficient. We will list those studies excluded after full-text assessment in the table 'Characteristics of Excluded Studies', giving reasons for exclusion.

#### **Data extraction and management**

We will develop a data extraction form based on the Cochrane Consumers and Communication Review Group's template, and pilot and amend it as necessary. We will extract the following main sets of data from each included study:

- lead author; date;
- study participant inclusion criteria;
- participants (participant diagnoses/condition(s) and demographics: race/ethnicity, gender, religion/culture, socioeconomic status, age);
- study design and timetable; randomisation; allocation concealment;
- interventions (content and format of interventions, including details of oral information or description provided; nature of results given to participants; actual diagnostic result; intervention setting and delivery provider; delivery of any co-interventions, theoretical basis of intervention if stated);
- numbers of participants in each trial arm;
- outcome measures; time(s) at which outcomes assessed;
- results;
- confounders;
- analysis;
- additional comments.

At least two authors will independently extract data to the data extraction form. The forms will then be checked by a third author and any errors or inconsistencies resolved. The first author will enter the data into RevMan, with another author checking the accuracy of data entry.

#### **Assessment of risk of bias in included studies**

We will assess and report on the risk of bias of included studies in accordance with the guidelines in the Cochrane Handbook for Systematic Reviews of Interventions ([Higgins 2008](#)), which recommends the explicit reporting of the following individual domains:

- Sequence generation;
- Allocation concealment;
- Blinding of participants, personnel and outcome assessors (assessed for each main outcome or class of outcome);

- Incomplete outcome data (assessed for each main outcome or class of outcome);
- Selective outcome reporting;
- Other sources of bias.

We will also examine and report the following:

- Validation and reliability of outcome measures;
- Whether the study obtained ethics committee approval and ensured informed consent for participation;
- Use of standardised protocols for information delivery. We will check for consistency of the delivery of interventions where possible.

Two review authors will independently assess the risk of bias in included studies, with any disagreements resolved by discussion and consensus, and with a third author acting as arbiter. We will present our assessment in risk of bias tables for each included study. We will contact study authors for additional information about the study methods as necessary. We will incorporate the results of the risk of bias assessment into the review through narrative description and commentary about each of the items mentioned. This will lead to an overall assessment of the risk of bias of the included studies (Ryan 2007).

#### Measures of treatment effect

We will analyse separately measures of motivation to engage in behaviour, and measures of actual behaviour. The nature of the measures used (for example, the content of questionnaire items or the objective instruments utilised) within each type of behavioural outcome may differ, but where regarded as comparable will be integrated and standardised to have common effect sizes. Effect size for continuous outcome measures will be defined as the standardised mean difference (SMD), with the effect size for binary outcomes being the odds ratio (OR). We will convert all effect sizes to OR for comparison. We will obtain a pooled effect size with 95% confidence interval (CI) using the random-effects model.

#### Dealing with missing data

We will conduct intention-to-treat analyses accounting for missing data where possible, and when this is not possible will analyse results as reported. For smoking cessation outcomes we will follow the principle that missing data is usually regarded as continued smoking. We will report on levels of drop outs in the intervention and comparison groups as an indicator of 'acceptability' of the intervention, and the likelihood of bias.

#### Assessment of heterogeneity

We will test for heterogeneity using the Chi<sup>2</sup> test and further quantify any heterogeneity using the I<sup>2</sup> statistic (which describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error). A value greater than 50% will be considered to represent substantial heterogeneity (Higgins 2003; Higgins 2008). We will investigate heterogeneity by assessing any contribution from outliers.

We will assess for publication bias using funnel plots to informally examine any relationship between study quality and effect size (Sutton 2000).

#### Data synthesis

We will conduct a narrative synthesis of the included studies, dividing them into clinical and non-clinical categories. Within these categories we will present studies' major characteristics and results. If the studies are sufficiently similar in terms of population, inclusion criteria, interventions and/or outcomes (including the time(s) at which these are assessed), we will consider pooling the data statistically using meta-analysis.

Fixed-effect models assume that exactly the same population effect size is obtained for all studies in the meta-analysis, while random-effects models allow for the possibility that population parameters vary from study to study. We have opted for a random-effects model, reflecting the heterogeneity likely to arise from the use of different settings, participant groups, disease areas, interventions and measures across the studies.

#### Subgroup analysis and investigation of heterogeneity

The included studies are likely to be heterogeneous in terms of the health condition being imaged, and the behaviours that could reduce health risks. We will consider this heterogeneity when evaluating the review's results, but will not undertake a formal subgroup analysis - due both to the likelihood of insufficient studies being found, and the lack of a clear clinical or theoretical imperative for such analysis.

#### Sensitivity analysis

We will remove the lower quality studies (median split based on aggregate risk of bias rating) from the analysis to check the robustness of the results. We will undertake further sensitivity analysis to examine the impact of missing data, comparing results following intention-to-treat analysis to data actually found.

#### Consumer input

The protocol and review will be peer reviewed by at least one consumer, as part of the Cochrane Consumer and Communication Review Group's standard editorial process. We will seek additional feedback from members of the Cochrane Consumer Network at draft review stage.

## ACKNOWLEDGEMENTS

The authors thank all those who have commented on the protocol throughout its development. In particular we would like to thank Megan Pictor (Review Group Coordinator), Sophie Hill (Coordinating Editor) and the editors and peer reviewers of the Cochrane Consumers and Communication Review Group.



## REFERENCES

### Additional references

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#### Bovet 2002

Bovet P, Perret F, Cornuz J, Quilindo J, Paccaud F. Improved smoking cessation in smokers given ultrasound photographs of their own atherosclerotic plaques. *Preventive Medicine* 2002;**34**:215–20.

#### Higgins 2003

Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**:557–60.

#### Higgins 2008

Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.0*. The Cochrane Collaboration, February 2008.

#### Hirschl 2004

Hirschl M, Francesconi C, Chudik M, Katzenschlager R, Kundi M. Degree of atherosclerosis predicts short-term commitment for smoking cessation therapy. *Preventive Medicine* 2004;**39**:142–6.

#### McClure 2002

McClure JB. Are biomarkers useful treatment aids for promoting health behavior change? An empirical review. *American Journal of Preventive Medicine* 2002;**22**:200–7.

#### MeSH 2008

US National Library of Medicine. National Library of Medicine - Subject Headings. <http://www.nlm.nih.gov/mesh/MBrowser.html> (accessed 23 July 2008).

#### Mitka 2005

Mitka M. Costly surge in diagnostic imaging spurs debate. *JAMA* 2005;**293**:665–7.

#### Ryan 2007

Ryan R, Hill S, Broclain D, Horey D, Oliver S, Prictor M. Study quality guide. Cochrane Consumers and Communication Review Group March 2007.

#### Sutton 2000

Sutton AJ, Duval SJ, Tweedie RL, Abrams KR, Jones DR. Empirical assessment of effect of publication bias on meta-analyses. *BMJ* 2000;**320**:1574–7.

\* Indicates the major publication for the study

## APPENDICES

### Appendix I. MEDLINE (Ovid SP) search strategy

1. exp diagnostic imaging/
2. diagnosis computer assisted/
3. (mri or magnetic resonance imaging or microscop\* or photograph\* or holograph\* or radiograph\* or spectroscop\* or stroboscop\* or subtraction technique\* or thermograph\* or tomograph\* or transilluminat\* or ultrasonograph\* or ultrasound or imaging or scan\*).tw.
4. 1 or 2 or 3
5. ((show\* or presented or presenting or presentation or display\* or given or giving or gave or receiv\* or provided or providing or provision or view\* or expos\* or intervention\* or motivat\* or inform\*) adj7 (image\* or imaging or picture\* or depict\* or recording\* or scan\* or photo or photograph\* or radiograph\* or tomograph\* or thermograph\* or holograph\* or ultrasound or ultrasonograph\* or visual\* or their or result\*)).tw.
6. (visual\* adj10 feedback).tw.
7. 5 or 6
8. 4 and 7
9. (adher\* or complian\* or noncomplian\* or motivat\*).tw.
10. patient compliance/
11. health behavior/
12. health knowledge attitudes practice/
13. risk reduction behavior/
14. attitude to health/
15. motivation/ or intention/
16. patient education as topic/
17. counseling/ or directive counseling/

18. or/9-17
19. 8 and 18
20. randomized controlled trial.pt.
21. controlled clinical trial.pt.
22. randomized.ab.
23. placebo.ab.
24. drug therapy.fs.
25. randomly.ab.
26. trial.ab.
27. groups.ab.
28. or/20-27
29. humans.sh.
30. 28 and 29
31. 19 and 30

## **HISTORY**

Protocol first published: Issue 4, 2008

## **CONTRIBUTIONS OF AUTHORS**

Writing the protocol: All

Developing the search strategy: GJH, TMM

Searching for trials: GJH, AV

Selecting trials: GJH, AV, MH

Data entry: GJH, AV

Analysis: GJH, MH

Interpreting analysis: GJH, TMM, MH

Drafting final review: All

Updating the review: GJH

## **DECLARATIONS OF INTEREST**

None known

## **SOURCES OF SUPPORT**

### **Internal sources**

- King's College, London, UK.

### **External sources**

- No sources of support supplied