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Using the Smiley Faces task to teach the fundamentals for good clinical trials

Helen McAneney[1], Lisa Maguire[2], Mike Clarke[3]

Corresponding author: Dr Helen McAneney h.mcaneney@qub.ac.uk

Institution: 1. Northern Ireland Methodology Hub, Centre for Public Health, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast, 2. Northern Ireland Methodology Hub, Centre for Public Health, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast, 3. Northern Ireland Methodology Hub, Centre for Public Health, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast

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Abstract

Background: Many factors need to be considered when designing a clinical trial. Although structures such as PICOT (Population, Intervention, Comparator, Outcome, Timeline) are helpful, people with little or no prior knowledge can find designing and implementing a trial to be overly complicated. We developed a simple exercise to illustrate key features of trials: the Smiley Faces task.

Aim: We describe how the Smiley Faces task can demonstrate the importance of good planning of trials and highlight pitfalls.

Method and Results: The Smiley Faces task is centred on the simple, intuitive task to “draw a smiley face”. It requires no existing knowledge about trials or research generally, but can be used to highlight key features of a trial; such as formulating the research question; planning for coding, collection and analysis of data; handling of missing data and drawing of conclusions. We present insights from conducting the exercise dozens of times and collecting hundreds of smiley face drawings in a range of educational settings.

Conclusion: The simplicity and accessibility of the task makes it relatively easy to demonstrate key points for careful planning of clinical trials. The approach is generalizable and applicable to researchers and teachers in a variety of medical settings.

Keywords: Design, Implementation, Planning, Teaching, Trials

Background

There are many methods and models implemented to educate and teach, with the goal of enhancing learning. The teaching content can be conveyed through analogies and examples, and/or by experiencing the situation within role model scenarios, thus making new and unfamiliar concepts more meaningful to the student, by connecting to what they already know. When used effectively, metaphors and analogies are a valuable pedagogical tool to enhance the learning experience (Harrison and Treagust, 2006). This is especially true within medical education where ideas are often complex and multi-faceted. Learning can be facilitated and interest increased by seeing the relevance of the learning (Young et al., 2015). As Young et al. state; “It is been recommended that evidenced based health care (EBHC) becomes a core component of the curriculum for all healthcare professional, since learning the fundamentals of research and how to apply an evidence-based approach are essential in the implementation of EBHC and subsequently improvement in the quality of health care.”(Young et al., 2014). It is known that the best options for improving EBHC knowledge, skills and attitudes, is by clinically integrating teaching and learning, although the method of delivery can vary from lecture-based to online teaching, interactive online courses to workshops, with varying degrees of success (Young et al., 2015; Young et al., 2014). However, although clinical trials are a key part of EBHC, they take many years to complete, much longer than a student module or educational term. Therefore, innovative ways to embrace the process of clinical trials need to be proposed, to allow students to critically reason through the essential steps of evidence-based medicine on the processes of clinical trials. This will allow them to understand the consequences and hence relevance of the decision-making process on the conduct of a trial. We propose just one such innovative method, the Smiley Faces task.

When designing a clinical trial, it is all too easy to get lost in the fine detail without taking an overview of the simple things that can cause problems. Researchers might overlook key factors such as how to cope if the format of the collected data is different to what had been expected, which might weaken the integrity of the study either in reality or in the perception of users of its findings. If the design and implementation of the trial is less than ideal, this can contribute to research waste and leading to misleading conclusions.

The development and use of the PICOT (Population, Intervention, Comparator, Outcome, and Timeline) structure for formulating research questions has helped in the design process for trials, in particular in the articulation of the scope of the study (Richardson et al., 1995; Haynes, 2006). But people working on trials also need to think carefully about other key, practical aspects for the trial's design, conduct, analysis, and interpretation. In this paper, we report a simple technique that may help people with these issues, which has been used in dozens of settings with hundreds of participants.

Our approach is based on the task of drawing a smiley face and does not require any prior knowledge or experience of trials or research more generally. This makes it particularly useful in the teaching context, as it is an easy to implement and understandable example to illustrate the basics of trials and to explore potential challenges. It can also be used when interacting with patients and the public about the rationale for a trial as a fair test of different interventions (Chen and Chalmers, 2015). The task is asking participants to complete what, at first, seems the simple and straightforward task of drawing a smiley face with no further details or guidance given. The dozens of sessions to date have allowed several key learning points to be made and produced a rich array of variations in the drawings (see Figure 1). The various drawings and interpretations allows one to explore and highlight issues that arise in many trials, and to emphasise key aspects of good trial design. In this paper, we show how getting a group of people to draw a smiley face provides a simple means for showing them how a lack of forethought might weaken a clinical trial and helps to highlight many key stages in planning and conducting reliable and robust clinical trials (Trewick et al., 2015).

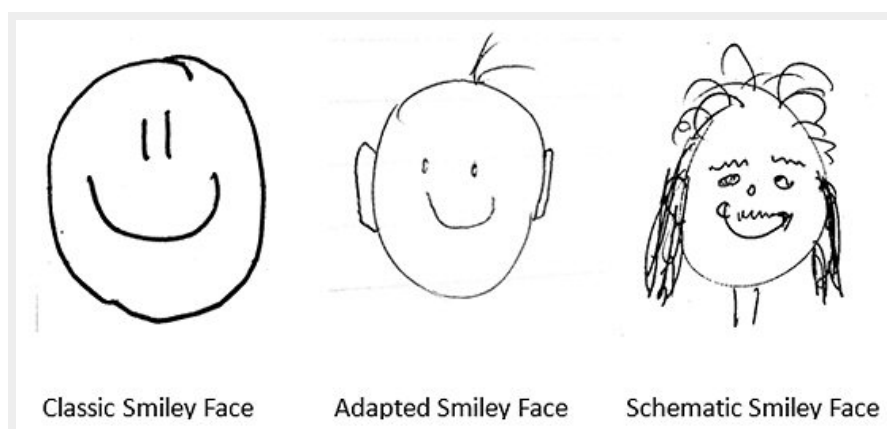


Figure 1. Examples of variations in participants' drawings produced as part of the Smiley Faces task.

Discussion of Key Learning Points

Determining the research question

Researchers planning a clinical trial should have a clear research question that they wish to investigate and which they will seek to answer in their study. The task of defining a research question lays the foundation for the work that will be done in the trial and will determine the methodology to use, data to collect, analyses to perform and conclusions to draw (Clouse, 2005; Thabane et al., 2009; Sackett and Wennberg, 1997; Stone, 2002).

In the Smiley Faces task, participants are simply asked to draw a smiley face and to write their name, gender and age, and the event at which the drawings were collected next to the drawing if they wish. No clear research question is presented in advance and, at the outset, they are not aware of the reasons for the task. This deliberate lack of an a priori research question is used to illustrate how the absence of a clear research question means that neither the researcher nor the study participants know how their data will be used, and how this lack of clarity generates doubt about which baseline and follow-up data are most important. After the faces have been drawn, the participants are asked to suggest possible research questions, which usually leads to a variety of ideas, some of which cannot be addressed fully by the collected data which is solely the drawings of the faces and the limited amount of information added to them by the participants. This illustrates how good trial conduct should ensure that the research question and the relevant data are clear in advance and communicated effectively to potential participants. The Smiley Faces task illustrates the dangers of formulating research questions *after* the data have been gathered, which leaves the way open for data-dependent biases, multiplicity, wasteful collection of data that will not be used, failure to collect the data that are most important and an inappropriate estimate of the sample size for the trial.

Choosing the main outcomes, collecting and coding the data





Researchers should decide in advance on the outcomes, how they will measure these *and* how they will code them for analysis. The development of core outcome sets (COS) can help when making decisions about *what* to measure (Gorst et al., 2016), and the use of a COS allows researchers to provide information that will help people making decisions and choices in the future. The Smiley Faces task helps the participants to consider what would be the key outcomes (perhaps using facial features as the analogy for outcomes in a trial) and to decide whether a small amount of simple data from a large number of participants (equivalent to getting lots of people to draw simple faces quickly) or a large amount of complex data from a small number of participants (equivalent to getting a few people to draw elaborate portraits) might be preferable when trying to answer their own research question.




The Smiley Faces task also shows participants the importance of considering how outcomes they measure will be coded or categorised for analysis. The task can be used to highlight the need to plan this and to be prepared for surprises. For instance, a plan might be to categorise the faces as:

- “Classic” smiley face - a circle with two black dots representing eyes and a simple arc representing a smiling mouth.
- “Adapted” smiley face - the classic smiley face but with added features, such as hair.
- Schematic face – a drawing depicting a more natural representation of a face.

However, as the examples in Table 1 show, the collected data might make it difficult to adopt this pre-planned categorisation. This can be used to highlight how it might have been better when designing the study to plan to categorise the data in a different way, such as the presence or absence of certain features. Adequate planning needs to take place for how the outcome data will be coded, both to minimise biases that might arise if the coding scheme is developed after the data have been collected and to anticipate resource implications such as the potential need for independent adjudication of some outcomes (Ndounga et al., 2016). These considerations might impact on how the data will be collected and avoid the need for post hoc changes to the plans.

Table 1. Illustrative examples of outcomes from the instruction to draw a smiley face.

Pictorial illustration ^a	Description of key features and variations	Potential Coding Framework (with variations)					
		Eyes	Mouth	Nose	Boundary	Ears	Hair
	Basic features: eyes and simple mouth	✓ (dots)	✓ (closed)	×	×	×	×
	Eyes and open mouth	✓ (dots)	✓ (open)	×	×	×	×
	Basic features with straight nose and eyes	✓ (dashes)	✓ (closed)	✓ (straight line)	×	×	×
	Basic features with oval nose and edged mouth	✓ (dots)	✓ (closed with edges)	✓ (open oval)	×	×	×

	Basic features with a boundary and eyes as circles and dots	✓ (circles with dots)	✓ (closed)	x	✓	x	x
	Basic features with a boundary, ears and hair	✓ (dots)	✓ (closed)	x	✓	✓	✓
	Artistic drawing in pen	✓ (open) Also eyebrows	✓	✓	✓	✓	✓ (wavy)

^aThese drawings of faces are used to illustrate typical features and possible variations which need to be considered.

Analyse the data

Having a statistical analysis plan in advance of examining the data should minimise biases that might arise from knowledge of these data, and ensure that the data are collected in ways that are appropriate for testing the trial's hypotheses and answering its research question. The Smiley Faces task can be used to highlight how even something as simple as this can leave the way open for many different types of analysis, including the problems of bias (Anon, 2017) and multiplicity (Bender et al., 2008). For instance, the variety of drawings shows that there are various approaches to analysis, which might include

- i. Frequency of single key features
- ii. Analysis of multiple key features or correlation of features via chi-squared tests
- iii. Logistic regression on binary features such as whether the facial features are bounded or unbounded and the inclusion of features which might depend on the presence of the boundary, such as ears or hair.

Furthermore, the statistical analysis plan should set out how the information collected on the participant's name, gender and age and the event at which the drawings were collected will be used in any subgroup analyses (Sun et al., 2014).

Other lessons that can be illustrated by the Smiley Faces task when the participants discuss the analyses of the data are:

- How and why the analyses will be done (including any statistical software that will be required and the coding frame to use)?
- The relevance of the collected data to the analyses that will answer the research question.
- What the analyses are intended to reveal or answer?
- How conclusive are the findings?

Missing data

The statistical analysis plan also needs to consider the approach to take to missing data and the Smiley Faces task shows how researchers will often be faced with missing data and need strategies to minimise or cope with this. Although all participants are asked to provide their name, gender and age, it is made clear that doing so is voluntary and some of them choose not to. This can provide the basis for a discussion of the implications of these missing data and strategies to minimise its impact, such as:

- Removal of the participants with missing data entirely from all analyses, raising issues about the value of the intention-to-treat principle and the possibility of bias.
- Limiting the analyses to the drawing of the smiley face alone and ignoring the additional information from all participants, raising questions about why the additional information were collected in the first place.
- Imputing the missing information from other data, raising issues about the appropriate way to do this.

Another opportunity to discuss the impact of missing data also arises when considering the drawing of the face, because an outcome that might be suggested for analysis is the size of the face. Although this might be straightforward if a boundary has been drawn around the facial features, some faces will be unbounded and an alternative measure of size might be needed, such as the distance between the eyes. The discussion can then focus on whether it is better for a study to have a proxy or surrogate measure such as this for all the faces or to have the primary measure for only some of them.

Taking these issues together, the Smiley Faces task stimulates thinking about the value of trying to collect the data that were missing, what it will be used for, whether data imputation will help or hinder the conclusions, and how to do any such imputation.

Interpretation and drawing conclusions

The conclusions drawn from the collected data of a well-designed clinical trial should be robust and reliable and be useful for decision makers in the future. The Smiley Faces task shows how a variety of conclusions can be drawn each time it is completed by a group, as these conclusions will often depend on the interpretation of the drawings that arise from the particular participant group. This is just the same as when multiple trials of the same topic are conducted and raise different results, then interpreting their findings in isolation from each other can lead to conflicting or contradictory conclusions (Clarke et al., 2010). Within the multiple groups who have completed the Smiley Faces task, some interpretations and conclusions occur repeatedly and others are novel, but all tend to have a basis in post hoc interpretation of the data that have just been collected. This reinforces the need for a clear research question for a clinical trial, such that the answer to this question can be used to underpin the trial's conclusions, rather than having these conclusions driven by the specific data sample collected.

Conclusions

Overall, we have shown how the task of drawing a smiley face can be used to reveal many important aspects that should be considered when designing, conducting, analysing, and interpreting a clinical trial. The exercise can be used as a simple teaching tool, which is relatively easy for a variety of professionals and the public to grasp. Drawing a smiley face is a task that people have engaged in from childhood but we do so in different ways. Given its simplicity, it can be used to inform trial participants of key elements in trial design, as well as highlighting potential pitfalls to those designing trials. It can also help to identify areas of uncertainty about the methods for the trial, which might be examined in a SWAT (Study Within A Trial) (Clarke et al., 2015).

In summary, we recommend that those who find themselves deep in the fine details of designing a trial should think of the task of drawing a smiley face and the lessons it can teach about planning research, collecting and analysing data and interpreting the results.

Take Home Messages

- The teaching of clinical trials is a key part of evidence based health care but an innovative method to convey the key aspects of good trial design is needed
- The Smiley Faces task provides a simple means to show how a lack of forethought might weaken a clinical trial and help highlight key stages in planning and conducting reliable and robust clinical trials

Notes On Contributors

Mike Clarke, BA, DPhil, is a Professor of Research Methodology and Director of the Northern Ireland Methodology Hub at Queen's University Belfast, and is the Director of the Northern Ireland Clinical Trials Unit.

Lisa Maguire, BSc, PhD, is a Research Fellow within the Northern Ireland Methodology Hub at Queen's University Belfast, UK.

Helen McAneney, MSci, PhD, PGCHET, is a Lecturer in Research Methodology at the Northern Ireland Methodology Hub at Queen's University Belfast, UK.

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Ethics approval and consent to participate

Not applicable.

Consent for publication

The three participants who drew the faces shown in Figure 1 have given their consent for these to be included.

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Authors' contributions

MC conceived of the idea, MC and HMcA collected the data, HMcA drafted the manuscript, and all authors revised the manuscript and approved the final version.

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Declaration of interests

The authors report no declarations of interest.

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Appendices

Declaration of Interest

The author has declared that there are no conflicts of interest.