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Clinical trials concocted for the classroom

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Abstract

We describe an activity that introduces school-aged children to clinical trials, that presents the terminology associated with randomized controlled trials, and that reveals how the findings from clinical trials are applicable to everyone everywhere.

KEYWORDS

practical activity, randomized clinical trials, teaching statistics

1 | INTRODUCTION

Clinical trials are research studies that test a medical, surgical, or behavioral intervention in people. They are the primary way that researchers determine if a new form of treatment or prevention, such as a new drug, diet, or medical device (for example, a pacemaker), is safe and effective in people. Often, a clinical trial is designed to learn if a new treatment is more effective or has less harmful side effects than existing treatment(s), or better than no treatment.[1]

According to data available on ClinicalTrials.gov, an online database of clinical research studies, by the end of 2022 437,530 clinical studies had been posted on the site since the inception of the database in 2000.[2] This translates as there being a large number of clinical trials running at any one time, including studies recruiting or specifically targeted at people aged 18 and under. Whilst there are about 10 times as many clinical trials involving adults as children in the United States of America,[3] a recent study conservatively estimated an enrolment of 717,000–2.87 million children using combined children/adult data.[4]

Given the importance of clinical trials, and the large numbers of children participating in clinical trials, the United Kingdom (UK) National Curriculum for Combined Science, and Biology includes brief content related to clinical trials.[5] The UK National Curriculum sets out the programs of study and attainment targets for all subjects at all four key stages (ages 5–18). Currently, the UK curriculum requires students to be familiar with the development and testing of new drugs, including the multiple stages of testing and evaluation of safety and effectiveness.

The terminology and concepts associated with clinical trials, and included in the Curriculum, are challenging to understand. Therefore, we propose a novel activity to demonstrate a clinical trial by running a simple trial within a classroom setting and thus introduce children to most aspects of trials. This will support teachers to deliver core content for key Stage 3 students (ages 14–16) and to introduce younger students to the concept in advance of their General Certificates of Secondary Education (taken in the United Kingdom by students aged 15–16).

Whilst classroom demonstrations of randomized controlled trials already exist, they tend to have a different focus to the situation seen in reality. For example, in Cancer Research's activity,[6] they encourage participants to test both interventions which is less common in clinical practice. Conversely, our study is more akin to reality and thus more suited to the national curriculum content. An alternative is the Northwest Associations for Biomedical Research's classroom activity.[7] This focuses on the challenges of recruitment and the phases of a clinical study, which is not the focus of the activity we describe.

The activity we have designed and describe here illustrates clinical trial contexts and concepts. The statistical learning within the activity includes the concepts of consent, randomization, allocation concealment, and blinding

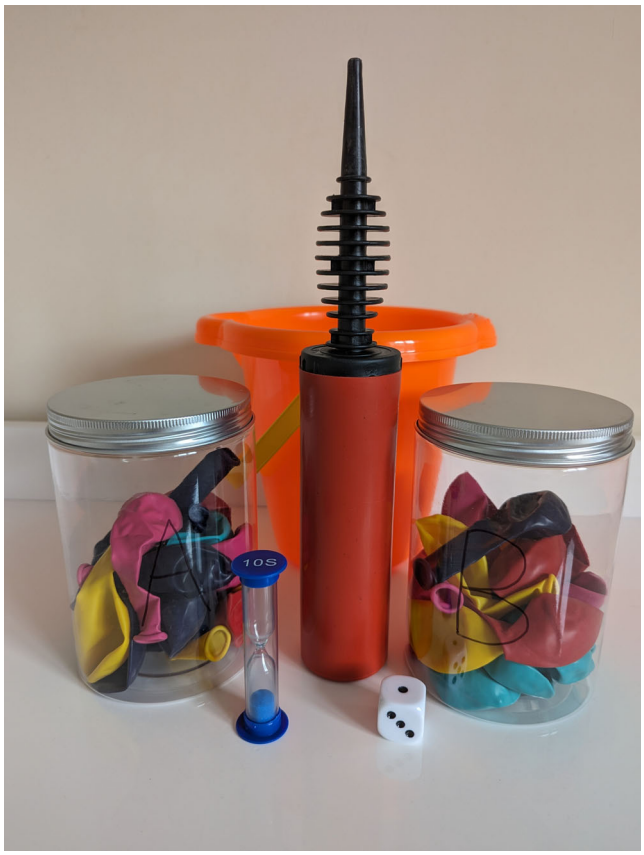

FIGURE 1 Required resources for the clinical trials activity.

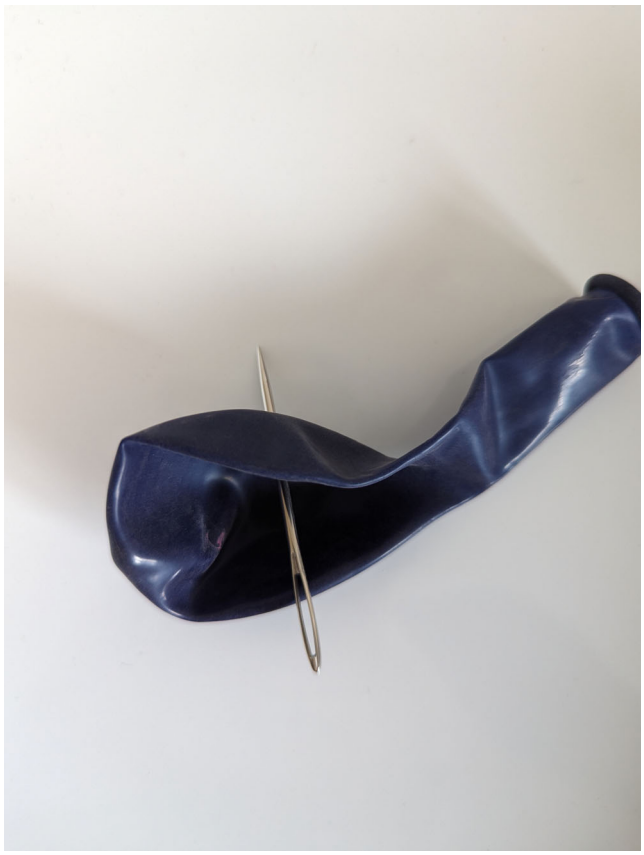

FIGURE 2 Sewing needle through the body of a balloon to create a large but unnoticeable hole.

within clinical trials and why such studies are vital in real-life. Our activity can be tailored to the available time, context, and level of the target audience. In the following sections, we present a suggested template for delivering the activity at a science festival exhibition or similar for single groups of students over a very short duration of time and as a classroom version with increased capacity and duration.

2 | MATERIALS

Our activity requires a die, and two identical jars containing similar but different contents, labeled jar A and jar B.

Our preference is to have uninflated standard (10–12 inch) balloons in one jar, and standard balloons with a small hole in the body in the other. In this setting, a bucket (from a standard children's bucket and spade set, our example is 15 cm wide at the opening) is also required, alongside a 10-s sand timer (or stopwatch or similar), and a balloon pump. The required resources for this activity are shown in Figure 1. Note that a longer sand timer (e.g. 15 s) and a smaller bucket can be used as required by the group, for example younger children or children with special educational needs.

Balloons are easy to source ensuring that the activity is ideal for science festivals and for use in the classroom. However, it must be noted that children under 8 years can choke or suffocate on uninflated or broken balloons and therefore should be supervised especially closely.[8] The use of a balloon pump minimizes this health and safety risk and ensures equality across all participants including those who have asthma or other lung conditions.

In our experience, the best way to make a relevant sized (yet still unnoticeable) hole in the balloon is to use a large sewing needle and insert it through both sides of the body of the balloon as shown in Figure 2.

Alternatives to balloons include bouncing and non-bouncing balls (with an outcome of five consecutive bounces for examples) and food items (taste test with chocolate and plain biscuits for example).

3 | THE ACTIVITY

Whilst clinical trials traditionally estimate a treatment effect or the effect of an intervention such as surgery, it is impractical and unethical to run a traditional clinical trial in the intended setting of a science festival or classroom. Therefore, we have opted for a simplistic activity of short duration to resemble a clinical trial.

TABLE 1 PICO statements for example clinical trial and clinical trial activity described in this article.

	Example traditional clinical trial	Clinical trial activity described in this article
P (population)	People with a headache	Balloons
I (intervention)	A new pain killer	Needle
C (comparator)	Paracetamol	No needle
O (outcome)	Pain score	Inflation of balloon to larger than the bucket

Clinical trials can be described according to the population, intervention, comparator, and outcomes (PICO) model.[9] A traditional treatment study may have the PICO shown in column two of Table 1 whilst the activity described in this article has the PICO shown in column three of the table.

Our activity, demonstrating a clinical trial, is designed to be run either as a 5-min activity at a science festival, or as a 20–60-min activity within the classroom. Information as to how to run both of these variations is provided below.

3.1 | Science festival (or similar)

Prior to the event, fill one jar with standard balloons (non-treated balloons) and the other with balloons with a hole in (treated balloons).

3.1.1 | Step 1: informed consent

The session leader should begin the activity by asking the balloon (i.e. student(s) 'become' the balloon) whether they would like to take part in the trial. Next, the session leader should explain that they (the balloon) may receive a needle (be treated) or may not. The session leader should also explain that the trial is trying to determine which treatment is best (which balloons are easiest to inflate). In real life, this may be a reduced risk of measles for example following vaccination. It should also be explained that balloons cannot choose whether to have the needle or not; the decision is made for them by the roll of a die. The leader then checks again whether the balloon would like to take part in our trial.

3.1.2 | Step 2: randomization

If the balloon agrees to participate then the leader explains that the balloon (student) should roll the die. If the die lands on an even number, the balloon is allocated to one arm of the clinical trial (needle, for example), and if it lands on an odd number, then the balloon is allocated to the other arm of the trial (no needle, for example). An alternative is to use a coin and allocate students to each trial arm based on a heads or tails response.

In this version of the activity, balloons have already been "treated" in advance of the randomization. Therefore, students at this point are allocated to choose a balloon from jar A for example if they roll an odd number, and from jar B if they roll an even number. Randomizing children to balloons which are already "treated" or not provides the same randomization effect as children being given a balloon and then randomizing which balloons have the needle intervention.

Teaching staff whom we have spoken to when designing this (and other) activities have said they appreciate the learning opportunity associated with a die. In particular, they can discuss probabilities which are more complex than 50:50, as well as odd and even numbers etc. For these reasons we prefer to use a die rather than a coin and thus our description of the activity continues assuming the use of a die.

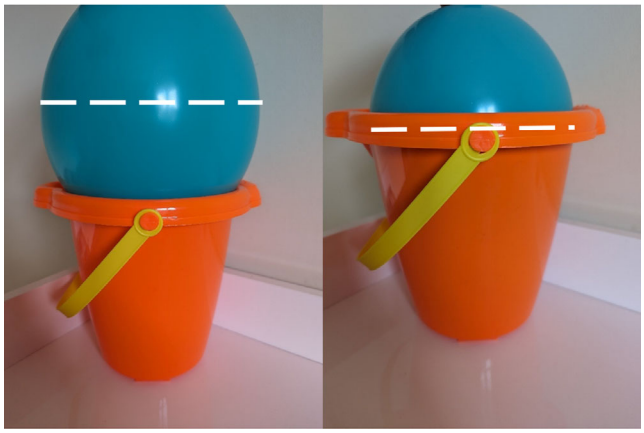

FIGURE 3 Demonstration of two possible outcomes following inflation of the balloon.

3.1.3 | Step 3: data collection

Once the student has rolled the die and selected a balloon, the leader asks the student to inflate the chosen balloon until it is too big to fit in the bucket. The leader should invert the 10- (or 15-) second sand timer to ensure all students are given the same length of time to complete the task.

Figure 3 shows example outcomes – the image on the left shows a successful outcome whereby the middle of the balloon, shown as a white dotted line, is too big to fit inside the bucket. The image on the right shows an

TABLE 2 Example tally chart for reporting of results.

		Jar A	Jar B
Balloon bigger than the bucket?	Yes		
	No		

unsuccessful outcome as the middle of the balloon is inside the bucket. An alternative outcome is that the balloon pops whilst being inflated. This is recorded as the balloon not being bigger than the bucket.

The results are then recorded on a simple tally chart which has four boxes as shown in Table 2. A mark is made in box "Jar A, Yes" if the student selected a balloon from Jar A and inflated it to be too big for the bucket for example. It is recommended to use five-bar gate notation to make counting easy (in groups of 5).[10]

3.1.4 | Step 4: data analysis

The activity is concluded by asking students to use the tally chart to collate the results of the experiment based on whether the balloon was inflated to be bigger than the bucket or not, and whether the balloon came from jar A or jar B. The table can then be visually inspected to determine whether balloons from jar A generally were inflated to be bigger than the bucket than those from jar B for example. (Note, this visual inspection will require data to be populated in advance of the event to ensure that the first few students can make this conclusion – data from our sessions with this activity can be found in the implementation section below.) The session leader should then explain that further analysis would then be required to fully interpret the data.

Finally, the session leader should go back through the activity using relevant terminology, namely, they should explain that initially balloons were invited to participate, then they consented (they agreed to participate) and randomized (die roll to determine which intervention they were allocated to, i.e., which jar they selected a balloon from), and then the results of the study were evaluated. Therefore, in this activity, students have been introduced to the main components of a clinical trial and the associated terminology using a simple experiment with balloons.

3.2 | Classroom extension

In the science festival exhibition version, the session leader asks a student to pick a single balloon from either jar A or jar B and then adds the result of the balloon inflation to a tally chart before briefly introducing each term associated with clinical trials. However, in a classroom activity it is possible to generate sufficient data to answer the question numerically, rather than by visually inspecting the data. Also, each term can be fully described and associated discussions initiated. Further, questions can be addressed such as what happens if a student picks a balloon from the wrong jar? What happens if a balloon changes its mind about being involved in the study? What happens if the person supervising the inflation of the balloons discards results which do not match the existing pattern in the tally chart?

To extend the science festival exhibition version, and to answer these questions, the experiment described above can be repeated, but using the entire class rather than a single student. In particular,

1. Ask students (on behalf of the balloons) to put their hands up if they would like to be involved in the trial.
2. Explain the study and ask again whether balloons (students) would like to be involved. If they would, get them to sign a piece of paper.
3. Explain how balloons (students) will be assigned to an intervention (jar) and explain the intervention – needle or not (contents of the jar – balloons with and without holes).
4. Ask each student to roll the die in turn. All students should roll the die before anyone selects a balloon from a jar to minimize the chance of students trying to roll a particular number on the die if they prefer jar A or B based on their fellow students' selection. In our experience, it is helpful to ask the students to stand in two distinct locations in the classroom depending on the outcome of their die roll to avoid students forgetting if they rolled an odd or even number.
5. Once all students are in the relevant location, ask them all to select a balloon from the relevant jar.
6. Each student should then perform the experiment and note their result on an overall class tally chart.
7. The session leader should then help the students to analyze the results, namely calculate a relative risk from the produced contingency table. Relative risk is a term used to describe the chance of a certain event occurring in one group versus another.[11] It is calculated as

$$\text{Relative Risk} = \frac{W/(W+X)}{Y/(Y+Z)}$$

with W to Z being generated as shown in Table 3.

8. Once the relative risk has been calculated and interpreted by the group, the session leader should reveal

TABLE 3 Example tally chart for reporting of results.

		Jar A	Jar B
Balloon bigger than the bucket?	Yes	Response W	Response Y
	No	Response X	Response Z

whether jar A was the undamaged balloons or damaged ones. To assist with the interpretation of the relative risk:

- a. If the relative risk is 1, then there is no difference in chance of inflating the balloon to be bigger than the bucket between balloons from jar A and jar B.
- b. If the relative risk is less than 1, then the chance of inflating the balloon to be bigger than the bucket is greater with balloons from jar B than jar A.[11]
- c. If the relative risk is greater than 1, then the chance of inflating the balloon to be bigger than the bucket is greater with balloons from jar A than jar B.[11]

Next, the session leader should remind students of each step of the study and introduce the relevant terminology. Namely, step 1 is the invitation to participate in the study. This should lead to a discussion about why people might not want to be involved – time limitations, not interested in the study, uncertainty as to the purpose of the study or how much involvement the study will comprise etc. Step 2 consents the balloons (students) into the study. Here, discussions could include why permission is required (active participation rather than passive) and why it is important to evaluate characteristics of people not consenting to be part of the study – to minimize bias in sampling.[1]

Step 3 describes random allocation and should discuss why students should not be allowed to make their own decision about which jar to pick a balloon from, why the session leader should also not be allowed to make their own decision, and how a die is a much more appropriate method of randomization – humans are not random but a die should be.[12] Students should also discuss other methods of randomization such as a random number generators.[13] The concepts of blinding and double blinding can also be introduced here – namely the participants or the participants and the researchers not knowing which study group the participants are in.

3.2.1 | Extension 1: intention-to-treat & per-protocol analysis

Three extensions to the study are possible to answer the three questions posed above. First, once fresh jars of balloons have been prepared the leader could ask students to roll the randomization die again and this time go immediately to jar A or jar B as relevant, remove a balloon, inflate it, and then record the result on a new class tally chart (as in Table 1). From experience, not all students will go to the correct jar. This may be because they have forgotten which numbers are allocated to which jar, or because they prefer one jar over the other. The session leader should keep a note of any student who takes a balloon from the wrong jar. If no students take a balloon from the wrong jar, then the session leader can describe a hypothetical situation whereby a couple of students take balloons from the wrong jar.

Once the tally chart is complete, the session leader should circle any results where the student took a balloon from the wrong jar. For example, if student 6 rolled a 2 but selected a balloon from jar B rather than A and managed to inflated their balloon to be bigger than the bucket, then the session leader should circle a tally marking in the 'Jar A, yes' square of the tally chart. Students should then be encouraged to discuss ways to handle this.

There are two approaches to handling students selecting a balloon from the incorrect jar – the intention-to-treat approach and the per-protocol approach.[1] In an intention-to-treat analysis, the results are analyzed based on the jars that students were initially allocated to.[1] So, in our example, the tally for student 6 should move to the 'Jar B, yes' square of the tally chart before the relative risk is calculated as they were randomized to jar B even though they took a balloon from jar A. In a per-protocol analysis, the results are analyzed only for participants who received the treatment or intervention to which they were initially allocated.[1] So, in our example, the tally for student 6 should be excluded from the tally chart. A discussion can then take place about the pros and cons of both approaches including the likely underestimation of the impact of the intervention and therefore the over-cautious nature of the approach with the intention-to-treat approach for example.[14]

3.2.2 | Extension 2: withdrawal

In the second extension, the experiment is run as before (once the jars have been freshly prepared). However, at each stage of the study, balloons (students) should be asked if they want to stop being part of the study. If they wish to withdraw, they should be encouraged to give a

reason such as "too tired". We usually find that at least one student does not want to inflate a balloon for a second or third time. If all students continue for the entire extension activity, then the session leader can describe the hypothetical situation of a student withdrawing from the study.

At the analysis stage, students should be encouraged to think about the implications of balloons withdrawing from the study. For example, if they withdrew before they were randomized, there is little impact on the study. However, if they withdrew after being allocated, or after attempting to inflate their balloon then there are implications for the calculations as the total number of balloons (students) has changed. It is also important to evaluate the reasons for the withdrawal – if all students said they were too tired then perhaps the design of the study should be modified to make it less tiring. Perhaps the size of the bucket could be reduced so that the balloon requires less inflation to be a successful outcome.

3.2.3 | Extension 3: allocation concealment & blinding

Allocation concealment

Allocation concealment describes the situation where the person randomizing the patient does not know what the next allocation will be. This is a way to prevent selection bias[1] and is demonstrated in our activity by the use of die to randomly select the next allocation of balloon to intervention (students to jars) – the session leader has no idea which jar the next student will be randomized to.

To demonstrate selection bias, the activity can be run as before (once the jars have been freshly prepared), but in this iteration, the session leader discards any results which do not neatly fit into the contingency table – namely the session leaders discards any results whereby the student did not inflate a normal balloon to be larger than the bucket, or whereby the student did inflate a damaged balloon to be larger than the bucket.

Blinding

The fourth extension is particularly appealing to students as they get to choose the allocation of balloons within the jars. Rather than the session leader setting up the jars, two students are invited to discuss and prepare the jars without telling the session leader which jar the damaged balloons have been placed into. The experiment then continues as before, but now only the two students know the allocation and they should not participate further in the experiment (until the reveal after the analysis of the contingency table). Just before the reveal, the session leader should explain that the study has just been run in a double-blind design, rather than the single-blind design of the initial experiment. The session leader should facilitate a discussion about double and single blinding including the removal of unfair influence by the session leader to inflate undamaged balloons over damaged ones for example when using a double rather than a single-blind design.

TABLE 4 Clinical trial terminology described in this activity, together with a brief definition for use within a game of 'terminology bingo'.

Term	Definition
Invitation	Asking a participant to join a clinical study
Consent	The purpose of the research is explained to the participant, including what their role would be and how the trial will work, and then they are asked if they want to take part
Randomization	The process of assigning participant by chance to groups that receive different treatments or interventions
Allocation concealment	The person randomizing the participant does not know what the next treatment allocation will be
Intention-to-treat	An assessment of the participants taking part in a trial, based on the group they were initially allocated to
Per-protocol	An assessment of the participants taking part in a trial, but only including those who received the treatment or intervention to which they were initially allocated
Withdrawal	The participant removes themselves from the study (or the doctor removes the participant from the study for clinical reasons)
Single-blind	The participants (or the doctors, or the assessors) do not know which study group they (the participants) are in
Double-blind	Neither the participants nor the researchers/doctors know which study group the participants are in
Relative risk	The chance of a certain event occurring in one group versus another
Contingency table (2×2)	A method for displaying data in four categories based on two factors, each with two possibilities

TABLE 5 Pooled results across all implementations to date.

		Jar A	Jar B	Total
Balloon bigger than the bucket?	Yes	6	26	32
	No	37	11	48
Total		43	37	60

The extension activities described above can be run in isolation after the initial running of the activity, or combined to make a full-length lesson.

3.2.4 | Terminology Bingo

To consolidate all the terms that have been introduced within the classroom activity, we advocate the use of 'terminology bingo'. In our version of bingo, students are presented with a 3×3 grid which contains the words that are covered by the activity (invitation, consent, randomized, allocation concealment, intention-to-treat, per-protocol, withdrawal, single-blind, double-blind, relative risk, and contingency table) included in a random order on each grid. The session leader then explains that the aim of the game is to mark off all nine terms listed on the card according to the definitions read out in a random order by the session leader; the first person to complete their card correctly wins a prize. The session leader then reads out brief definitions of each term in a random order giving students a few seconds to mark their sheets after each definition is read with the appropriate term. Brief definitions are provided in Table 4 as a guide.[1]

4 | IMPLEMENTATION OF THE ACTIVITY

We have run the classroom version of this activity with year 5 and 6 pupils (9–11-year-old children) and the science festival version with youth group participants (aged 5 – adult). Our learnings from these sessions have been reflected in this version of the activity, particularly the use of a sand timer to ensure consistency in the time provided to attempt to inflate the balloon. Additionally, the activity benefits from the opportunity to use a smaller/larger bucket and a longer/shorter sand timer depending on the audience (adults vs. younger children or children with special needs for example).

Table 5 shows the pooled tally chart for all implementations of the activity to date. We advocate use of the five-bar gate notation but have used English numerals for typesetting convenience here. Results are presented such that jar A is the balloons with holes (treated balloons), and jar B is the untreated balloons. The relative risk for these data is 0.20 demonstrating that the chance of inflating the balloon to be bigger than the bucket is 80% greater with balloons from jar B (untreated) than jar A (treated).

In our experience, most balloons with holes in (treated balloons) burst whilst being inflated and are thus scored as "no" within Table 5. Many students can inflate the balloon to be bigger than the bucket within the timeframe if the balloon does not have a hole in it, but difficulties with getting the balloon onto the pump sometimes mean that they cannot. This can be overcome by permitting students to prepare the balloon and the pump before commencing the sand timer.

Terminology bingo has only been used with year 5 and 6 pupils to date. In these groups, the terms allocation concealment, intention-to-treat and per-protocol were the most frequently forgotten – at the end of the game when the session leader had read all the definitions, these were the words most frequently left unmarked on the bingo cards. Students also regularly confused relative risk and contingency table; they understood that the two terms were related to one another but often struggled to differentiate the definitions.

5 | CONCLUSION

Clinical trials are a core component of the National Curriculum in the United Kingdom and a large number of adults and children are involved in active clinical trials. However, the terminology associated with clinical trials is unique to its field and can be challenging to understand. A basic understanding of clinical trials has many real-life implications, namely, increased confidence in prescribed medications, increased likelihood of agreeing to participate in a future clinical trial, and increased knowledge of an underlying condition or clinical studies in general.[1] We therefore propose a novel way of demonstrating a clinical trial, in particular a randomized controlled trial, that can be utilized as a quick-hitting activity at a science fair, or as a more in-depth classroom activity. The method described in this activity is used in reality, and thus, the activity could run in conjunction with a science class.

The science festival exhibition version and all associated extensions of the activity introduce students to the concept of clinical trials via an experiment with balloons. Students (acting as balloons!) are encouraged to participate in a randomized study which they consent to be part of and contribute to the analysis of the results. In particular, they are required to think about intention-to-treat and per-protocol analyses, the implications of withdrawals from the study, and the challenges and benefits of double blinding over single blinding of a study.

We appreciate that our 'toy example' does not fully reflect a randomized controlled trial. We have not used medicines (for obvious reasons), and we have designed an activity which can be concluded within 5–60 min rather than the usual 12 months plus for standard randomized trials. For sessions leaders who see pupils repeatedly over a longer period, it would be possible to modify this activity from balloon inflation to seed germination or similar. Students could be randomized in the way described above, to germinate cress or similar seeds in two different ways – perhaps on a windowsill or in a cupboard for example. This would facilitate discussions about drop-outs or death within a clinical trial, as a result of prolonged involvement in the study, as well as the terminology described within this activity.

By demonstrating to students that a simple experiment with balloons can be used to demonstrate a clinical study, we hope to convince students of the real-life benefits and challenges of randomized controlled trials whilst helping them to remember terminology required for their compulsory exams at ages 15 or 16.

CONFLICT OF INTEREST STATEMENT

The authors declare conflicts of interest.

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