Original Article

Can an online approach to citizen science revolutionise clinical trials?

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The problem with traditional clinical trials

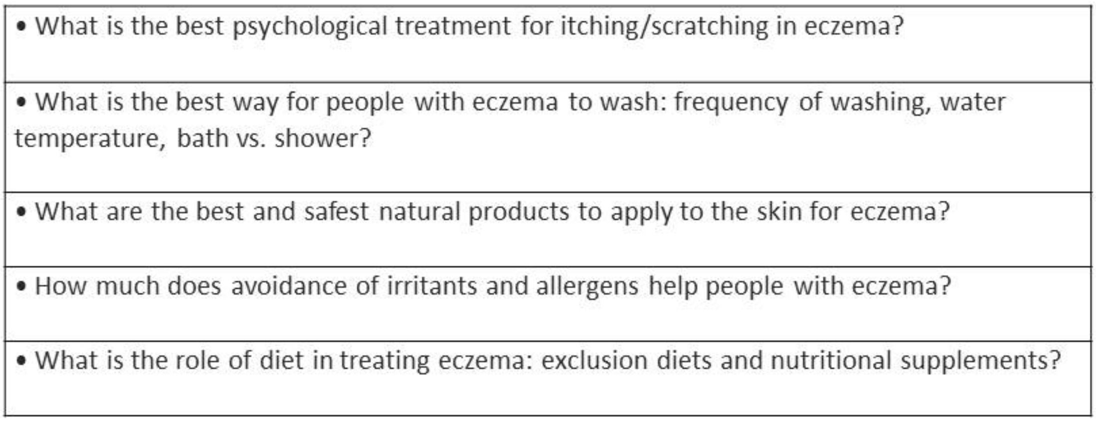
Clinical trials are often regarded as the cornerstone of evidence-based research (Sackett and Cook, 1994). They are the 'gold standard' for evaluating new treatments and approaches in healthcare and the methodology is becoming increasingly sophisticated (Bhatt, 2010). They form the basis of systematic reviews that provide the evidence that clinicians, policymakers, and guideline developers look to when implementing changes in clinical practice. Trials have changed the landscape of healthcare. However, there are still some major challenges with the way clinical trials are currently conducted, which we will highlight with some examples from our research of eczema (syn. atopic dermatitis).

Firstly, high-quality later phase clinical trials can be expensive and time-consuming to conduct. It can take years for a large pragmatic clinical trial to be funded and delivered - typically costing over one million British pounds in the UK, and costs are rising (National Institute for Health and Care Excellence, 2019). As an example of how high quality trials take a long time to complete, the results of an eczema prevention trial that started in 2014 were published 8 years later (Chalmers et al., 2020). Costs, capacity, and time issues mean there are questions of importance to patients, carers and clinicians that will not be prioritised for high quality research, creating a bottleneck of evidence generation.

Secondly, research questions for clinical trials do not always address what matters most to patients. This might occur for a multitude of reasons, such as financial incentives and goals of organisations, or limited resources available to investigate certain topics. However, one of the reasons could be because patients are not involved in designing and leading the research, and patient and research priorities do not always align. For example, our team noticed that from a priority setting exercise for eczema research over 10 years ago, the shared priorities between patients and healthcare professionals and those of healthcare professionals have mostly been addressed, but the patient priorities remain relatively under-researched (Batchelor et al., 2013). Table 1 shows these patient priorities.

Thirdly, findings from clinical trials are not always integrated into clinical practice, indicating issues around implementation (Ashrafzadeh et al., 2020, May et al., 2009). For example, there is

Table 1
Patient priorities from the James Lind Alliance Priority Setting Partnership (Batchelor et al., 2013).



• What is the best psychological treatment for itching/scratching in eczema?
• What is the best way for people with eczema to wash: frequency of washing, water temperature, bath vs. shower?
• What are the best and safest natural products to apply to the skin for eczema?
• How much does avoidance of irritants and allergens help people with eczema?
• What is the role of diet in treating eczema: exclusion diets and nutritional supplements?

evidence from clinical trials dating back to the 1990s that once a day topical corticosteroid use is as effective as twice a day use, however this finding has yet to be implemented as a recommendation in UK eczema guidelines and become standardised within practice (Lax et al., 2022).

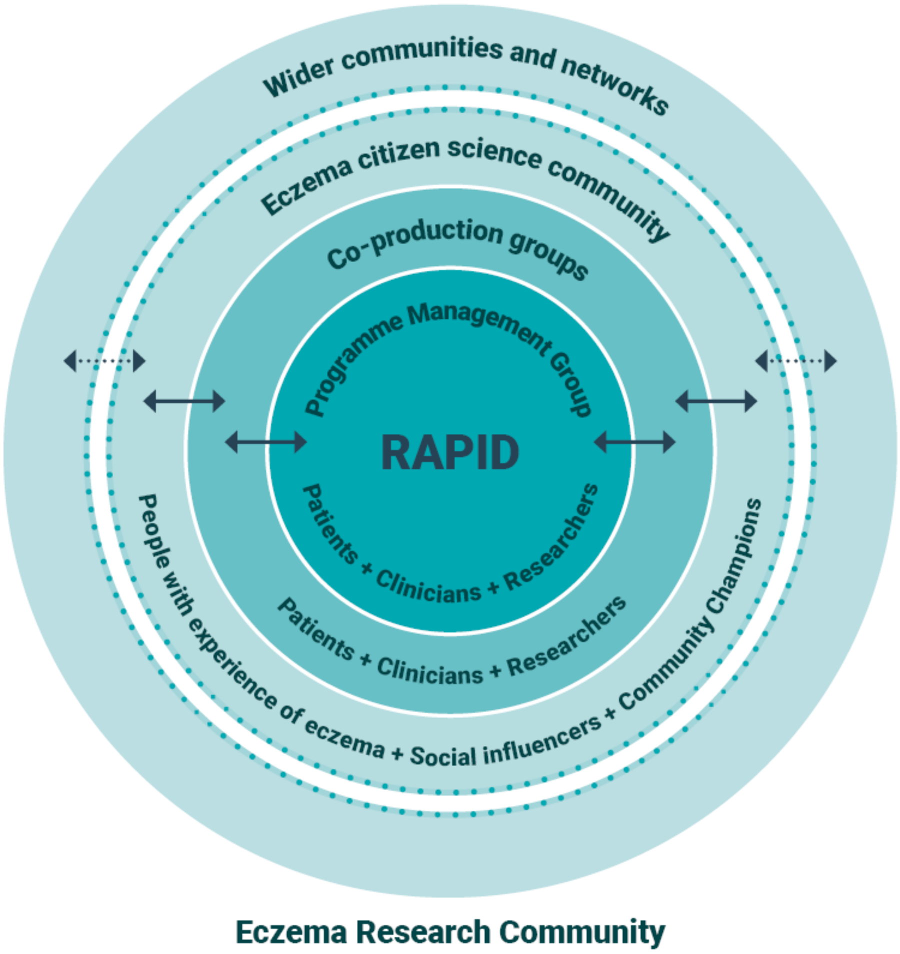
A new citizen science approach: Rapid Eczema Trials

The Rapid Eczema Trials project wants to deliver a paradigm shift in clinical trial design. Our aim is to deliver efficient and meaningful trials that improve the lives of people living with eczema by placing people living with eczema at the centre of research as well as creating an efficient model of delivery. Three workstreams all put "citizen scientists" (members of the public) at the centre. Citizen science can be varied in its definition, and models for how citizen science can be used in health research vary (Borda et al., 2019, Heigl et al., 2019, Robinson et al., 2018), but our working definition is 'a scientific method of working with members of the public to define, address and share answers to questions that are important to them'. There are various levels at which citizen scientists can be involved in the project (Figure 1).

Workstream 1 focuses on developing a "Eczema Citizen Science Community" of people living with eczema, carers, researchers and healthcare professionals from all areas across the UK. We hope that thousands of people will join the community. The community have options for how they input to the research design. All receive a regular newsletter from the study team with relevant updates and opportunities to get involved. Some opt in to participate in remote consultation exercises, such as online surveys or discussion groups. Those who want to be more involved can join a co-production group. The co-production groups are where members of the public, healthcare professionals and researchers work together to prioritise and formulate the research questions, design trial interventions (what approach is going to be tested out in the trial), establish control groups (what approach the intervention will be tested against), and design the trial features (e.g., eligibility criteria, length of trial, outcome measures). Additionally, the community will also have the opportunity to take part in the clinical trials. We have a payments policy where different levels of involvement allow for different levels of reimbursement informed by national guidelines (National Institute for Health and Care Excellence, 2022).

Workstream 2 delivers the online eczema trials

Figure 1. The Rapid Eczema Trials ecosystem



that have been designed by the co-production groups. The aim is to produce a minimum of three completed trials within the five-year funded research programme. To enhance efficiency, we will use a master protocol, and follow some key principles, so that the main processes are shared across all trials while allowing for specific design decisions to be tailored to each research question. By harnessing the power of the "Eczema Citizen Science Community" developed in workstream 1, and utilising online methods, we anticipate that recruitment will be more efficient compared to 'traditional' clinical trials. The trial will be delivered entirely remotely, thus reducing site-based costs and burden of follow up visits to clinics. We will be trialling new online methodologies for assessing eczema severity developed at Imperial College London (https://fundingawards.nihr.ac.uk/award/NIHR204505). Using a machine learning (artificial intelligence) tool, we plan to analyse photographs that participants take of their own eczema.

Workstream 3 accelerates uptake of new knowledge. People with eczema often lack information about their eczema, and the information they do receive is often conflicting (Santer et al., 2015, Teasdale et al., 2017). The Rapid Eczema Trials project aims to ensure that the evidence generated as part of the research programme reaches the people that need this information. Knowledge mobilisation is about 'moving knowledge to where it can be most useful' (Ward, 2017). To accomplish this, a knowledge mobilisation co-production group comprising members of the public with experience of eczema alongside healthcare professionals and researchers will be established. Their collective effort will span throughout the programme to design ways to get eczema evidence and knowledge about research to the people who need it in a way that is helpful for them. The programme will also work with 'community champions' who will go into their communities to find out their needs. This workstream will also include a process evaluation guided by the '10 principles of Citizen Science' and the 'Open Framework for Evaluating Citizen Science' (Robinson et al., 2018, Kieslinger et al., 2018). We will use demographic data to assess the reach of diversity in the community. We will collect qualitative data to explore how they benefit from taking part.

Pushing the boundaries of research

In many ways, Rapid Eczema Trials is not using new approaches, but pushing the boundaries of patient involvement and trial efficiencies.

Patient involvement: Involving patients in setting research priorities and designing trials is not a new concept (Partridge and Scadding, 2004, Petit-Zeman et al., 2010, Batchelor et al., 2013, Williams et al., 2022). Rapid Eczema Trials wants to build on this involvement by creating a 'citizen science' eczema community. The hope is that this community acts as an engine for generating knowledge via trials by supporting the design and development, spreading the word to support recruitment, taking part in trials, and supporting the dissemination and mobilisation of knowledge.

Trial efficiencies: Trials have been using online methods for several years. In terms of eczema research, recent trials have demonstrated the successful delivery of fully online trials (Santer et al., 2022, Baker et al., 2022, Baker et al., 2023). Rapid Eczema Trials seeks to build on these efficiencies to deliver multiple trials using a master protocol and standardised templates for study materials. The hope is that this approach creates efficiencies in the trial lifecycle, ultimately facilitating a more streamlined and efficient delivery of clinical trials.

Why is this relevant to health psychology?

Many of the research questions we will answer in the Rapid Eczema Trials are likely to have a psychological component to them. For instance, the top patient priority from the eczema priority setting exercise was "What is the best psychological treatment for itching/scratching in eczema?"(Batchelor et al., 2013). Clinical trials are an important method for testing health psychology interventions (Marks and Yardley, 2004). Evidence also suggests online intervention effects are comparable to face-to-face interventions and usually more cost effective and scalable (Andersson, 2018). New methodologies that allow for rapid set up and delivery of psychological interventions are needed.

What next

Does this streamlined approach to designing, delivering, and disseminating trials by harnessing the power of citizen science make efficiencies in research? Does it produce useful, meaningful trials? Does it create evidence that will reach the people who need it? We hope to find out as we embrace citizen science and new methodologies in the Rapid Eczema Trials project. We hope to make our materials widely available, so others can design their own rapid trials.

To follow the work of the Rapid Eczema Trials project, visit https://rapideczematrials.org/

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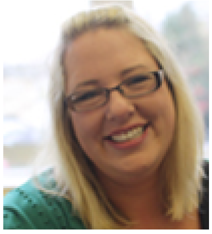

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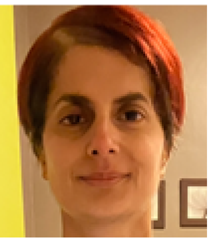

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