

Imperial College  
London

# The path to doing a clinical trial

*A workshop as part of the  
NW London Research Symposium for NMAHPPs*

Dr Shawn Walker, [Shawn.Walker@imperial.ac.uk](mailto:Shawn.Walker@imperial.ac.uk)

Researcher in Residence, Clinical Academic Training Office / ICHNT

Honorary Consultant Midwife

NIHR Advanced Fellow

1

An innovation I have  
taken down the path  
to a clinical trial

2

An innovation I hope  
to take down the  
path to a clinical trial

3

An innovation you  
could evaluate in  
your own setting

- Problem and broad context for the study

NIHR Fellowships: What is the problem being addressed?

- Need for the study made clear

NIHR Fellowships: Why is this research important in terms of improving health and/or wellbeing of the public and/or to patients and health care services?

- What is already known

NIHR Fellowships: Review of existing evidence

- Purpose / Aim or Question for the study

NIHR Fellowships: What is the research question / aims and objectives?

The screenshot shows the Imperial College Healthcare website. The header includes the NHS logo, 'Imperial College Healthcare NHS Trust', and navigation links for 'WORKING HERE', 'PROVIDING HEALTHCARE', 'A-Z', 'NEWS', and 'WHO WE ARE'. A search bar and user profile icon are also present. The breadcrumb trail reads: 'You are here > Home > A-Z > Research > Research > Developing your research proposal'. A 'Research' dropdown menu is open, showing 'Share this' and 'Like' options. The main heading is 'Developing your research proposal'. Below the heading, it states 'Published: 06/05/2020 Last Updated: 25/05/2022' and 'Key Page'. The text describes the page's purpose: 'This page takes you through all the stages of developing a research proposal. This section charts the evolution of the research proposal process, from developing your research question to funding your study, involving patients and the public and ensuring your research meets good governance expectations. The information in this section is to help you get started on constructing and implementing your own research project. It offers practical help and advice and useful web-based resources to enhance your development as a researcher by demystifying the processes of research governance, achieving funding and instigating your research. On this page:'. A list of links follows:

- [How to get started](#)
- [Is my research idea important?](#)
- [Is my project research?](#)
- [Contracts for sites hosting research](#)
- [Costing your project](#)
- [The Allied Health Professionals' Careers Resource](#)
- [Developing a research protocol](#)
- [Applying for a fellowship](#)
- [Involving patients and the public in health research](#)
- [Early engagement and PPI](#)
- [The role of NIHR patient research ambassadors \(PRAs\)](#)
- [Useful web links in planning and implementing a research project](#)
- [CAHPR Top tips for research](#)
- [Health Research Authority resources](#)
- [NIHR NWL CRN App for portfolio study information](#)
- [NIHR Nursing and Midwifery Incubator Network](#)
- [Standard Operating Procedure for Non Commercial Grants and Fellowships](#)

- The **Library** can help with a literature review
- Start with **Patient and Public Involvement** – small grants
- Consider publishing a **professional article** outlining the need for the research
- A track record of publications will be important for **funding applications**

The screenshot shows the Imperial Clinical Trials Unit website. At the top, there is a navigation bar with links for 'Study', 'Research & Innovation', 'Be Inspired', and 'About'. Below this is a secondary navigation bar with links for 'About the unit', 'Therapeutic areas', 'Contemporary Clinical Trials Course', 'Patient and Public Involvement', 'Clinical Data Systems', 'ICTU News and Events', 'Quality Assurance', and 'More'. The main content area features a sidebar on the left with a 'Contemporary Clinical Trials Course - Update' section, which states that the next course will be running from Tuesday 12th March to 4th June 2024, and that the course application system will open in November 2023. The main content area has a heading 'Contemporary Clinical Trials Course' and a sub-heading 'ICTU CONTEMPORARY CLINICAL TRIALS'. Below this, there are two expandable sections: 'WHY IS ICTU RUNNING THIS COURSE?' and 'WHO SHOULD APPLY?'. A 'More News' button is visible in the top right corner of the website screenshot.



Home / Study with us / Courses / Master's degrees / Clinical Trials by Distance Learning

## Clinical Trials by Distance Learning

(Certificate, Diploma and MSc)

**Overview** | Structure | How you study | Fees & funding | Entry requirements | How to apply

Share

### Overview

This programme provides students with a theoretical and practical understanding of the issues involved in the design, conduct, analysis and interpretation of randomised controlled trials of health interventions. It is suitable for students working in low-, middle- and high-income countries.

The need for rigorous evaluation of components of health care is increasingly recognised worldwide. An important type of evaluation is the randomised controlled clinical trial. The course will give students an understanding of trials which will equip them to work in this increasingly important field.

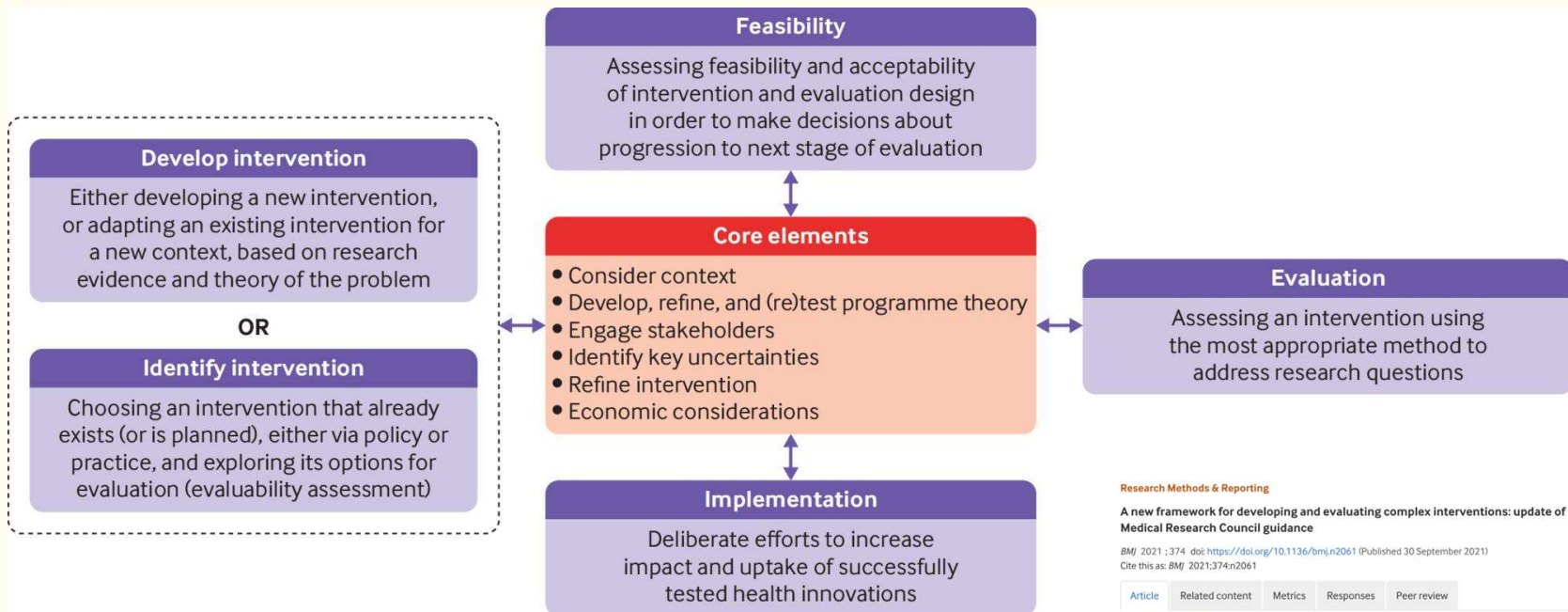
The programme is suitable both for those wishing to gain an overall understanding of trials before moving into

#### Admissions status

● Applications open for 2023/24

**Application deadline: 31 October**

Apply now



Research Methods & Reporting

**A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance**

BMJ 2021;374 doi:https://doi.org/10.1136/bmj.n2061 (Published 30 September 2021)

Cite this as: BMJ 2021;374:n2061

Article Related content Metrics Responses Peer review

Kathryn Skivington <sup>1</sup>, Lynsay Matthews <sup>2</sup>, Sharon Anne Simpson <sup>3</sup>, Peter Craig <sup>4</sup>, Jane M Blazeby <sup>5</sup>, Neil Craig <sup>6</sup>, Emma McIntosh <sup>7</sup>, Jo Rycroft-Malone <sup>8</sup>, Martin White <sup>9</sup>, Laurence Moore <sup>10</sup>

<sup>1</sup>research fellow, <sup>2</sup>research fellow, <sup>3</sup>professor of behavioural sciences and health, <sup>4</sup>professor of public health evaluation, <sup>5</sup>professor of public health and epidemiology, <sup>6</sup>professor of surgery, <sup>7</sup>reader in health economics, <sup>8</sup>acting head of evaluation within Public Health Scotland, <sup>9</sup>professor of health psychology, <sup>10</sup>professor of health economics, <sup>11</sup>professor of public health evaluation, <sup>12</sup>faculty dean, <sup>13</sup>professor of population health research, <sup>14</sup>unit director

Author affiliations

Correspondence to: K Skivington [kathryn.skivington@glasgow.ac.uk](mailto:kathryn.skivington@glasgow.ac.uk)

Accepted 9 August 2021

## Example: Heads Up Clinic

What is the problem?

Why is this important?

Review of existing evidence

Research questions ...

46 NANA helpline: 0300 223 0400 (FRIDAY, MAY 31, 2013) **Doctors Daily News**

**FEATURE** Like us on Facebook  [www.facebook.com/body](http://www.facebook.com/body)



**■ The Heads Up! clinic at the James Paget Hospital in Gorleston offers women the chance of a natural birth for their breech babies.** Picture: PA

### A Heads Up! for women with breech babies

**W**hile the words breech and caesarean have traditionally gone hand in hand, a new service – the only one of its kind in the UK – is offering women the chance to deliver their Heads Up babies naturally.

Based at the James Paget Hospital in Gorleston, it has been developed by breech specialist midwife Sharna Walker and clinical midwifery manager Ann Walker with support from Cindia Martin, head of midwifery labour ward lead Vandana Choudhary and medical director Nick Orlaya.

The Heads Up! clinic and ante-natal classes, which are also open to women from outside of the Great Yarmouth area, offer access to specialist support, counselling and information for women whose babies are presenting breech (bottom or feet down) from 36 weeks.

This includes discussion of a range of ways of trying to turn a baby the right way along with what happens if a woman goes to the later stages of pregnancy and the baby is still breech – and it is not automatically a caesarean, as once might have been the case.

Sharna, who has been running the clinic on a Thursday for about a year, but is switching to Monday afternoons and evenings to allow more people to attend, said: “I’m very woman-led in my practice, if I meet a couple and I feel they are not interested or it will make them uncomfortable to talk about alternative therapies, I won’t do it.”

“My job is not to present a world view that the woman doesn’t already possess, if it’s not part of the way she currently approaches health and wellness in her life, I’m not going to try to convince her. The reality is that quite a few women use complementary therapies, which are thought to be safe if properly supervised and, while there is no clear evidence base which says they are effective, I think women like to do something to overcome or normalising their baby’s chance of having a safe birth.”

“If self-help techniques does not work, we offer external cephalic version (ECV). And then we discuss options for the birth. My job is to give information in a non-biased and non-judgemental way and then we work together as a team to support the woman’s choices.”

Most babies who are in breech at 36-40 weeks will turn themselves into the headfirst position and only 14% of pregnancies end up being breech, which can lead to a greater chance of complications.

Because caesareans have, in recent years, been the norm for breech babies, some midwives and doctors have had fewer opportunities to gain experience of vaginal breech birth, which is why many hospitals do not support that option.

Sharna, herself a mother of four, is an obstetrician by birth, one naturally trained there but then took UK qualifications when she moved here, which she finished in 2010.

“I was an independent midwife for about three years and I found a lot of people were contacting me because they wanted support to have a natural breech birth. I was willing to support them but there are increased risks with breech vaginal birth – although most of those can be met adequately by just being in an environment where you have immediate access to surgical delivery, if you need it, immediate access to paediatric help and provided the person with you has

### Pre-doctoral (2012)

- PPI and small research project
- Competencies for ECV practitioners (Delphi)

### Doctoral (2013)

- Systematic review of breech training
- Competencies for upright breech birth (Delphi)
- Grounded theory – how professionals learn

### Post-doctoral (2020)

- Feasibility and pilot testing – OptiBreech
- Further qualitative work

Substantive trial would begin in 2024 / 2025 if funded



## Example:

Midwife-led post-dates clinic

Induction of labour with complementary therapies

*Let's plan this out ...!*