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**Northumbria
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13th May 2015



Northern Regional Study Day

Research: How does it affect Practice?

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13th May 2015



Northern Regional Study Day

- ✿ The importance of research: past, present and future
- ✿ Types of Research
- ✿ Clinical Trials
- ✿ Using research findings in practice

Importance of Research: Past, Present & Future

RESEARCH THROUGH THE YEARS



1798 First Successful Vaccine

developed by Edward Jenner and introduced to combat Smallpox.



WHO certified the eradication of Small in 1979. Today **many vaccines are now available** including MMR, BCG, Meningitis, HPV, Hep B & Flu.



1928 Discovery of Antibiotics

Alexander Fleming was the first to suggest that the Penicillium mould must secrete an antibacterial substance, and the first to concentrate the active substance which he named penicillin.



300 million prescriptions for antibiotics issued in the US. Over 100 different antibiotics available to cure minor, as well as life threatening infections.



1978 IVF

The pioneers of this historical landmark were two British doctors, Dr. Robert Edwards and Patrick Stepbe who materialised the test tube baby after ten years of hard research.



Over **5 million** IVF babies born world wide.

Importance of Research: Past, Present & Future



QUESTIONS raised about research?

What is research?

Who does research?

Why do research?

When should you do research?

Is it hard to do?

How long does it take?

Will it make a difference?

Where can I find out more about research?

Types of Research & EBP

✿ Definition:

✿ “Research is the systematic and rigorous **process of enquiry** which aims to **described** phenomena and to develop and **test** explanatory concepts and theories. Ultimately it aims to contribute to a scientific **body of knowledge**. More specifically... it aims to ***improve health, health outcomes and health services.*** ”

Bowling (2009, p.1)

Evidence Based Practice

Clinical Trials

Qualitative research study

Cohort Studies

Systematic Reviews

Case Control Studies

Meta-analysis

Editorials

Expert Opinion

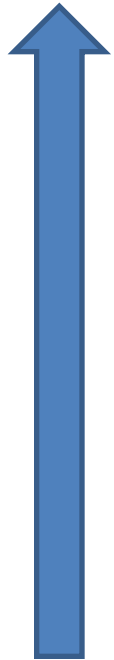
Case Reports

RCT's – Randomised Control Trials

Types of Research & EBP

✿ The Evidence Base Hierarchy

High Quality

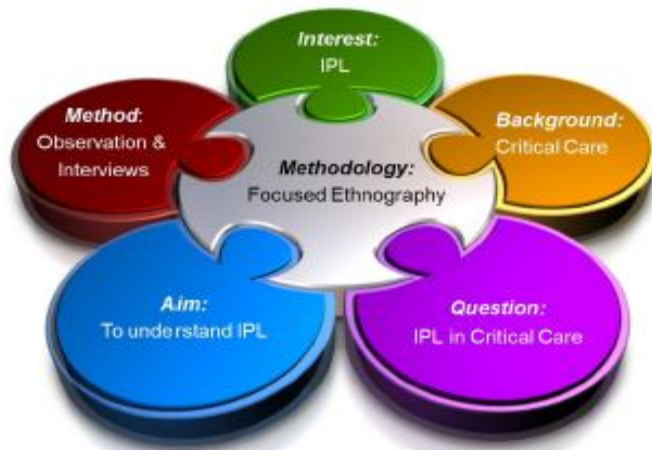


Types of Research & EBP



Inter-Professional Learning in Adult Critical Care

Vikki Park



Research title

An ethnographic study of the Inter-Professional Learning culture of NHS staff within the adult critical care clinical setting.

Background

Critical care is acknowledged as a complex and fast-paced care environment (Rothschild et al. 2005). The intensive level of patient care results in frequent interactions between different professional groups, therefore potentially increasing opportunity for collaborative practice and Inter-Professional Learning (IPL) to occur in this particular clinical setting. A body of evidence is accumulating to support the potential benefits to patients, staff and organisations as a result of Inter-Professional Learning through interprofessional education and collaborative practice (Reeves et al. 2009). However, research into Inter-Professional Learning within the specific area of critical care is limited. My research aims to explore this further.

For the purpose of this study IPL is defined as:

- Learning which happens between different occupational groups through the collaborative sharing of expertise, knowledge and experience.

Research Design

Aim

- To understand Inter-Professional Learning occurring within the specific culture of adult critical care.

Objectives

- To develop a rich description of the Inter-Professional Learning culture in adult critical care clinical practice.
- To understand in-depth critical care practitioners' perceptions and experiences of Inter-Professional Learning within adult critical care clinical practice.
- To identify which factors are perceived to promote or inhibit effective Inter-Professional Learning.

Methodology

A naturalistic qualitative approach will be adopted using ethnography to observe the interprofessional interactions of NHS critical care staff which may present learning opportunities within their natural setting, and in their 'natural state' (Hammersley and Atkinson 1997).

"Ethnographic research aims to provide rich, holistic insights into people's views and actions as well as the nature of the location they inhabit through the collection of detailed observations and interviews (Reeves et al. 2008 p.512)."

Focused ethnography has been chosen, also known as micro-ethnography, to focus upon one distinct issue within a culture in specific settings (Cruz and Higginbottom 2013). Using focused ethnography the distinct issue of IPL will therefore be explored specifically in adult critical care settings.

Method

- | | | | |
|-------------|---|-------------|--|
| ● Stage I: | Partial-participant observation | ● Stage II: | Interviews |
| ● Sample: | Three adult NHS critical care units
All professionals within the environment | ● Sample: | n= 4-12 per critical care department
4 occupational groups: Nurse, Doctor, Health Care Assistant, Physiotherapist |
| ● Duration: | Observations spanning 4 months per unit | ● Duration: | Individual interviews ≤ 1 hour |

Coming to a Critical Care Unit near you?

It is proposed the research will take place within three units within the North of England and the research is currently undergoing stages of ethical approval.

References:

- Cruz, E.V. and Higginbottom, G. (2013) The use of focused ethnography in nursing research *Nurse Researcher* 20 (4) pp.38-43
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- Reeves, S., Kuper, A., and Hodges, B.D. (2008) Qualitative research methodologies: ethnography *British Medical Journal* 337 (7688) pp.512-514
- Rothschild, J.M.; Landrigan, C.P.; Cronin, J.W.; Kessler, R.; Lockley, S.W.; Burdick, E.; Stone, P.H.; Lilly, C.M.; Katz, J.T.; Czeisler, C.A. and Bates, D.W. (2005) The Critical Care Safety Study: The incidence and nature of adverse events and serious medical errors in intensive care *Critical Care Medicine* 33 (8) pp.1694-1700

Types of Research & EBP

✿ The Evidence Base Hierarchy



Research in Critical Care?

- ✿ Many Current trials occur in Critical Care
- ✿ Below: Trial data taken from the CRN portfolio on the 1st May 2015

Export to Excel	Study Status			
Subtopic	In set-up	Recruiting	Closed / Suspended	All
CriticalCare	<u>9</u>	<u>52</u>	<u>139</u>	<u>200</u>

The grid above shows current activity in the portfolio and may not list every Subtopic.

- ✿ Examples from practice:
 - [Current](#)
 - VAP2 – Rapid detection and treatment of **V**entilator-**A**ssociated **P**neumonia towards antibiotic stewardship.
- ✿ [Previous](#)
 - Oscar: **O**scillation ventilation in **AR**DS
 - SPOT(light): **S**epsis **P**athophysiological & **O**rganisational **T**iming
 - ProMISe: **P**rotocolised **M**anagement in **S**epsis
 - GRiP: Does GM-CSF restore neutrophil function in critically ill patients?

ProMISe (Protocolised Management In Sepsis)

What is ProMISe?

A multi-centre, randomised controlled trial of the clinical and cost-effectiveness of early, goal-directed, protocolised resuscitation for emerging septic shock

An important, collaborative, NIHR-funded research effort between emergency, acute and critical care medicine

Primary objectives

- To estimate the effect of early, goal-directed, protocolised resuscitation compared with usual resuscitation on mortality at 90-days.
- To compare the incremental cost-effectiveness, at one year of early, goal-directed, protocolised resuscitation versus usual resuscitation.



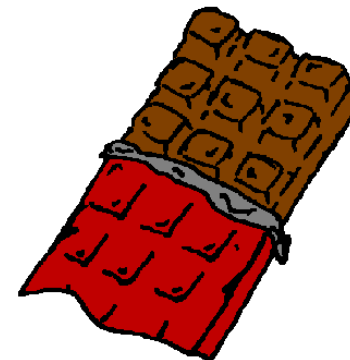
Understanding Clinical Trials

International Clinical Trials day – 20th May.

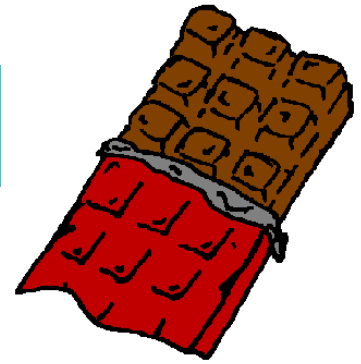
- “International Clinical Trials Day is celebrated around the world on or near the 20 May each year, to commemorate the day that James Lind started his famous trial on the deadly disease scurvy. It provides a focal point to raise awareness of the importance of research to health care, and highlights how partnerships between patients and healthcare practitioners are vital to high-quality, relevant research.”

NIHR (2014)

The Chocolate trial was designed
to raise understanding of
clinical trials during a previous International
Clinical Trials Day event.



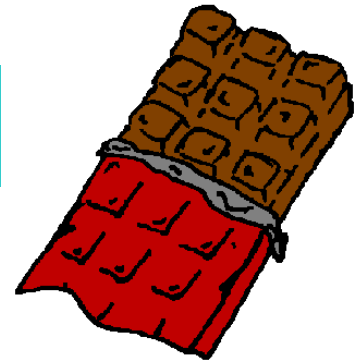
The Chocolate Trial



Stage	Instructions
Enrolment	<ul style="list-style-type: none">• Would you like to volunteer for the chocolate trial?• n= 6-10• Review the “Participant Information Sheet”• Are you eligible to take part in the study?• Do you consent to take part?

The Chocolate Trial

Participant Information Sheet



We would like to invite you to take part in our research study, "Chocolate".

Before you decide to take part we would like you to understand why the research is being done and what it would involve for you.

What is the purpose of the study?

Chocolate is a delicious treat to enjoy and satisfy hunger at any time, but it could be that the addition of a little flavour will make it even more satisfying.

We are holding a trial today to see if participants find the new chocolate and flavour more satisfying compared to the standard chocolate flavour.

Eligibility

To be eligible to take part in the trial you will need to be willing to eat the piece of chocolate and provide feedback. You will not be able to take part if you don't like chocolate, are lactose intolerant, or suffer from any food allergies.

N.B. THE INGREDIENT LISTS FOR BOTH PRODUCTS ARE AVAILABLE ON REQUEST.

What will happen to me if I take part?

If you have agreed to take part:

You will be randomly allocated to receive either a piece of standard chocolate or new chocolate. You have an equal chance of getting either.

You will be asked to eat your chocolate straight away and not save it for later.

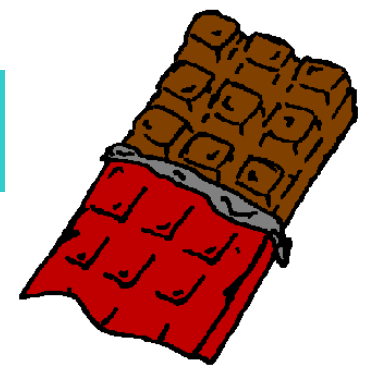
You will then be asked to provide feedback on the chocolate eaten.

Do I have to take part?

Taking part in the trial is entirely voluntary and you may withdraw your consent at any point without giving a reason.

Thank you for taking the time to read this sheet.

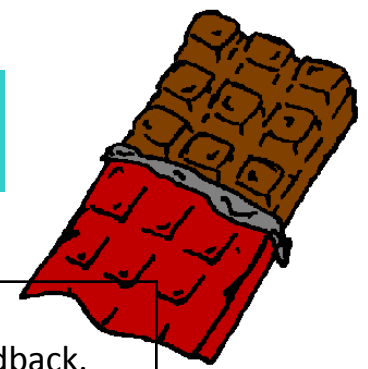
The Chocolate Trial



Stage	Instructions
Allocation	<ul style="list-style-type: none">Participants are randomised to one of two arms of the trial.<u>Pick a piece of paper from the bag</u>You will be given either chocolate 1 or chocolate 2 corresponding to the number drawn.

Key points for discussion
<ul style="list-style-type: none">Randomisation is important to this study.The experimental arm is the treatment being tested, and the control arm is either a placebo or the best current treatment for the condition (as in this case).In a real trial blinding is important. If possible neither the participant or the study team should know who has been given the experimental treatment and who is in the control/-placebo arm.In emergencies the study can be un-blinded.

The Chocolate Trial



Follow-Up	Once you have eaten your chocolate (taken your treatment) please feedback.
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Chocolate Trial Feedback Sheet

Please put a circle round the statement that best applies to you today.

Which chocolate did you eat today? Option One Option Two

Now that you have eaten your chocolate – do you feel hungry?

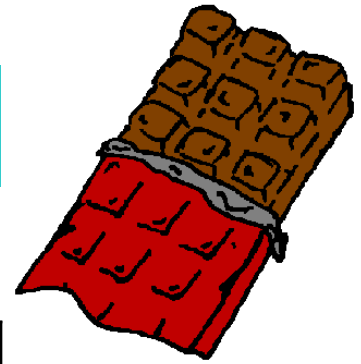
Very Hungry A Bit Hungry Ok Not Hungry At All

Have you learnt more about taking part in a clinical trial?

Not At All A Little Bit Quite A Lot A Lot

Thank you for taking part in the Chocolate Trial

The Chocolate Trial

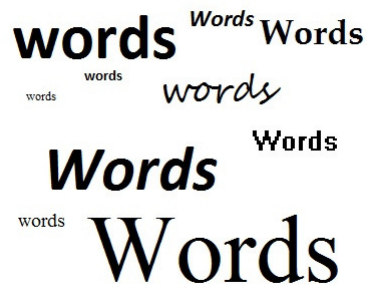


Analysis	<ul style="list-style-type: none">• Data will now be analysed.• Results will be published and disseminated.•?
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Quantitative

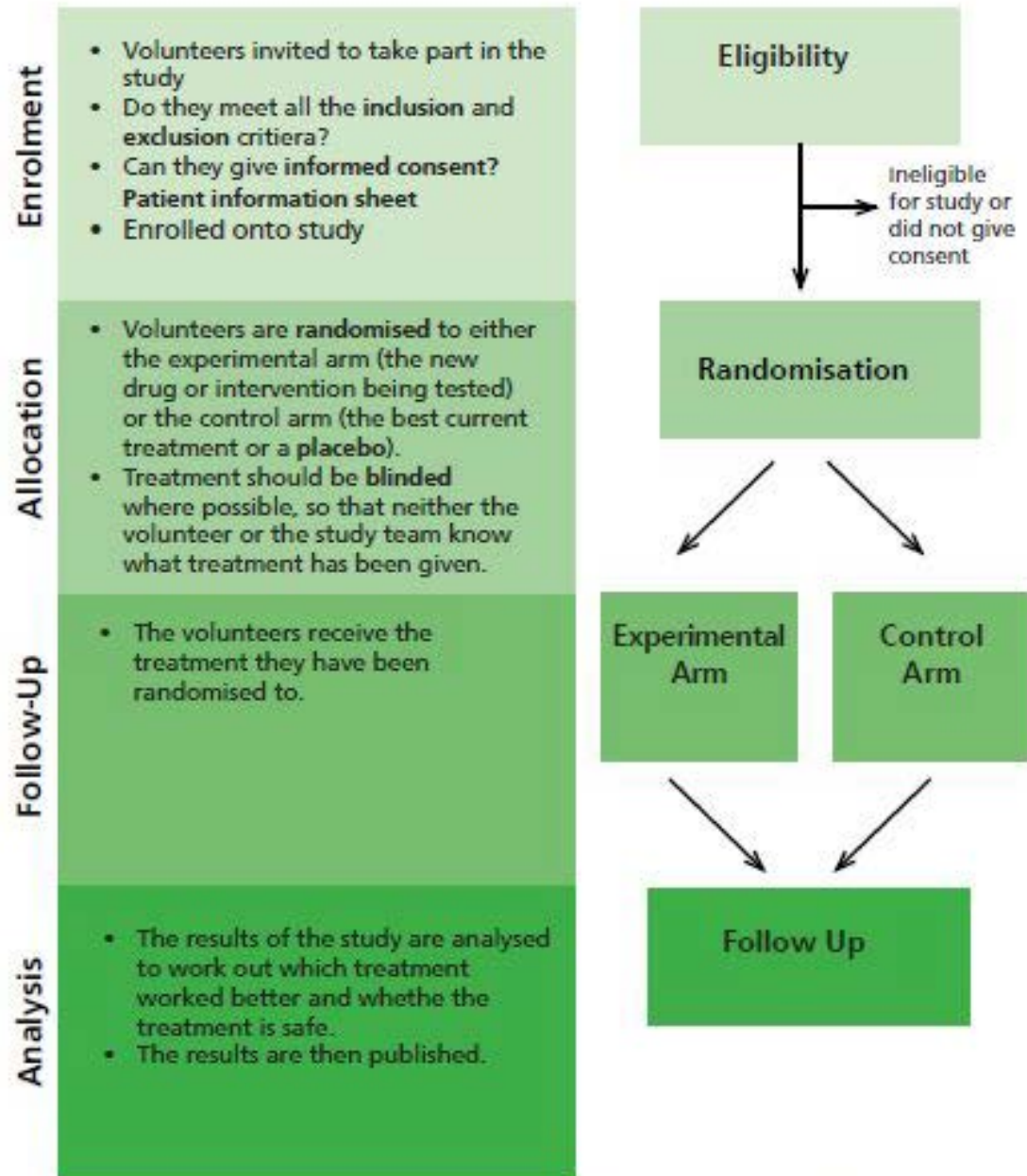


Qualitative



Mixed Methods

A Randomised Control Trial



ProMISe (Protocolised Management In Sepsis)

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ProMISe (Protocolised Management In Sepsis)

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Screening/Eligibility

Eligibility needs to be confirmed as soon as possible. The following four inclusion criteria must be met, at any time, in any order, and just once and within six hours from presentation at the emergency department:

- suspected or confirmed infection;
- two or more SIRS criteria;
- evidence of refractory hypotension or hypoperfusion;
- IV antimicrobials commenced.

Primary objectives

- To estimate the effect of early, goal-directed, protocolised resuscitation compared with usual resuscitation on mortality at 90-days.
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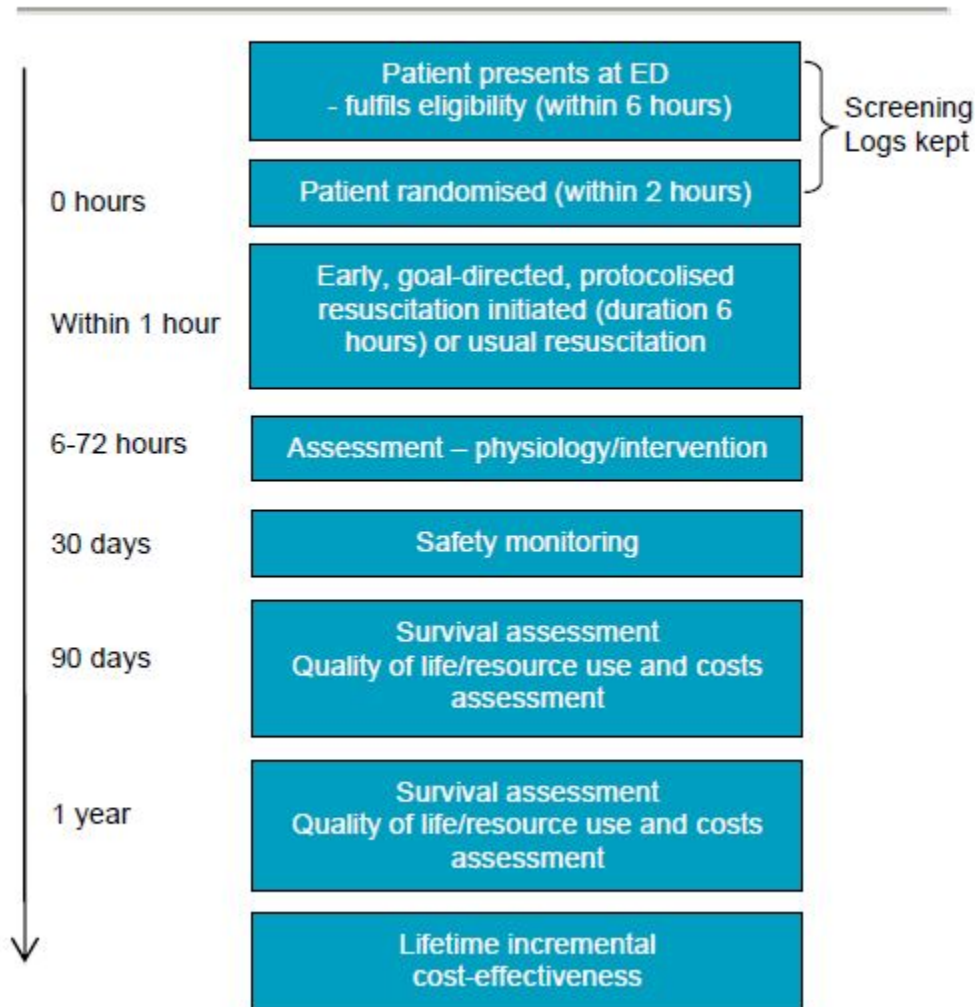
Randomisation

As soon as eligibility criteria are met, consent and randomisation should be completed within two hours.

Following randomisation, early, goal-directed, protocolised resuscitation commence as soon as possible or usual resuscitation continues as directed by the treating clinician(s).

ProMISe (Protocolised Management In Sepsis)

Timeline



Results ???

Results

QE Hospital: 90 day mortality: **29.5%** in treatment arm compared to **29.2%** in control arm.

Essentially NO difference!

Q. But could there really be?!

- ✿ **Some of the problems experienced with recruitment.**
- ✿ A&E not referring every patient that met the criteria
- ✿ Timeliness of referrals (missed recruitment)
- ✿ Bed pressures within Critical Care

What happens next?

- ✱ **The impact on practice:**

Changes to policies, procedures and the body of knowledge/Evidence Based Practice

- ✱ **Future research:**

Build on knowledge gained, develop/test theories, try new interventions, combine findings.

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Changes to policies, procedures and the body of knowledge/Evidence Based Practice

✿ Future research:

Build on knowledge gained, develop/test theories, try new interventions, combine findings.



ProMISe is complemented by two similar trials internationally:

- **ProCESS**
Protocolized Care for Early Sepsis Shock
- **ARISE**
Australasian Resuscitation In Sepsis Evaluation

An individual patient data meta-analysis will be performed across the three trials.

13th May 2015



Northern Regional Study Day

✿ **The importance of research: past, present and future**

- *Research informs and guides future practises*

✿ **Types of Research**

- *There are many different types of research and the research design should fit the research question*

✿ **Clinical Trials**

- *Data from clinical trials are considered to be of high quality and often lead to direct influences on practice*

✿ **Using research findings in practice**

- *Research influences clinical practice in a variety of ways. Ranging from using EBP to taking new approaches to care.*

13th May 2015



References

Northern Regional Study Day

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- NIHR (2014) *International Clinical Trials Day* Available at: <http://www.nihr.ac.uk/get-involved/international-clinical-trials-day.htm> Accessed on: 01.05.2015
- **Additional resources:**
- Clinical Research Network <http://www.crn.nihr.ac.uk/>
- ICNARC Publications <https://www.icnarc.org/Our-Research/Studies/Promise/Publications>