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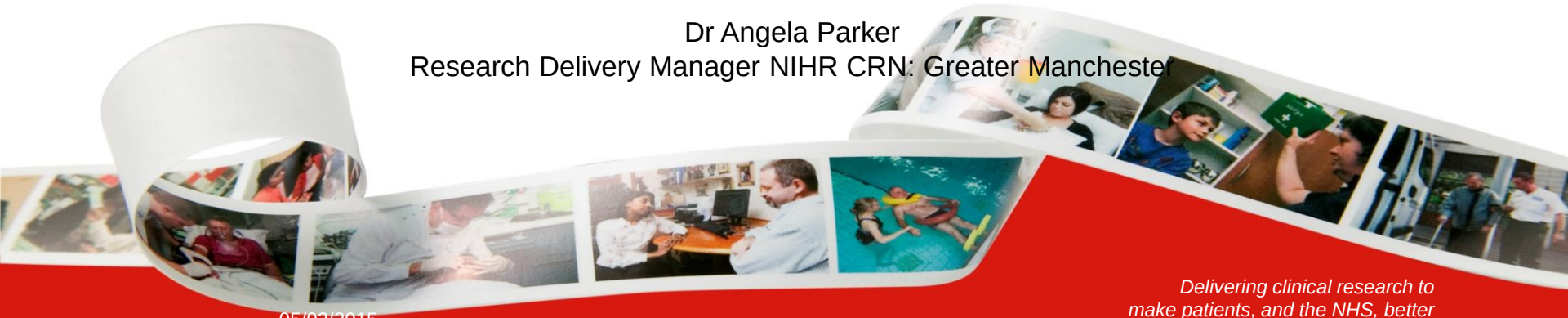
Are you asking me to be a guinea pig?

The Role of Clinical Trials in Dementia

Dr Angela Parker
Research Delivery Manager NIHR CRN: Greater Manchester



Delivering clinical research to make patients, and the NHS, better

Who am I and why am I here?

- *"Research is a core part of the NHS. Research enables the NHS to improve the current and future health of the people it serves. The NHS will do all it can to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them. The NHS is therefore putting in place* procedures *to ensure that patients are notified of opportunities to join in relevant ethically approved research and will be free to choose whether they wish to do so." NHS Constitution*

- **NIHR Clinical Research Network** –provides infrastructure to support high quality world-class clinical research within the NHS

Clinical Research Designs for Dementia

Observational:

- Case reports/case series
- Cross-sectional surveys
- Case control studies
- Cohort studies

Randomised:

- Clinical trials *

*the only way to reliably compare the effects of different treatments by controlling for inherent bias

- Sir Austin Bradford Hill: MRC trials on streptomycin for TB (1952)
- Basis for evidence-based medicine

Randomised Clinical Trials for Dementia

- **Key feature**: evaluates a therapeutic intervention in the most reliable way possible

- **Randomisation**:
  - the process of allocating treatments to two or more groups of participants by chance
  - Allows the two groups to be balanced for known and unknown variables

Randomised Clinical Trials: Key protocol issues in dementia

- **Blinding**:
  - "double bind": neither investigator nor participant is aware of the treatment allocation
  - Single blind – only the investigator is aware

- **Eligibility**:
  - defines the type of patient for a trial: Typical inclusion criteria:
    - Diagnosis of Alzheimer disease, mild to moderate stage
    - MMSE 12-24
    - Currently on cholinesterase inhibitor for at least 6 months
    - Age 65 to 85
    - Carer who knows the patient can participate as well
    - No clinically significant depression or history of sign vascular risks
    - Capacity to consent

Randomised Clinical Trials: Key protocol issues in dementia

- **Outcome measures**:
  - Cognition: MMSE, ADAS-Cog, other cognitive tests
  - Behaviour: Neuropsychiatric Inventory
  - Function: IADL scale
  - Caregiver burden: Zarit Burden Inventory
  - Quality of life: EuroQOL
  - Health Economic measures
  - Global Impression of Change: ADCD_CGIC

What happens if I am in a clinical trial?

- Eligibility screen
- Approach for consent
- Patient information given
- Informed Consent taken
- Screening visit
- Baseline measures
- Randomisation to study arm
- Study drug supplied
- Ongoing monitoring for safety (phone, visits-adverse Event Reporting)
- Ongoing monitoring for efficacy (visits)
- Study taper and termination(notification of study arm allocation)

What happens if I am in a clinical trial?

- Some studies may involve a certain degree of inconvenience or burden.
  - Having to stay in hospital for a while
  - Having to fill out lengthy forms and questionnaires
  - Having to be available for several visits perhaps at inconvenient times
  - Having to travel to where the research is being carried out
  - Being observed or monitored/Invasion of privacy e.g. having interviewers in one's home
  - Being asked about or reminded of very personal issues
  - Sticking to strict guidelines e.g. with regard to behaviour, exercise or diet
  - Being subjected to various tests e.g. blood tests, scans, tests involving reaction times or memory

Are there any risks taking part in research?

- Unrealistic expectations about the drugs' efficacy
- No access to drug after the trial even if there was a positive effect
- Interference with personal treatment plan
- Unforeseen side effects: unpleasant, serious or even life-threatening
- Having foregone other recognised treatment possibilities
- Being in the placebo group
- The frustration of not knowing which group one is in

Are there any advantages taking part in research?

- To do something different and challenging
- To contribute towards the possibility of finding a cure
- To have a closer alliance with a treatment team
- To promote self-management of one's condition
- To help manage feelings of helplessness

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Are there any advantages taking part in research?

- To exercise one's autonomy and take an active role in society
- To have the possibility of being prescribed a novel therapy particularly since no disease modifying drugs are yet available
- To access treatments which are not yet widely available
- To have the chance to improve one's own condition, wellbeing or quality of life

LINKS

National Institute for Health Research
Clinical Research Network Greater Manchester

- http://www.livewelldementia.co.uk/informational-videos/ Information about being part of a clinical trial-patient and carer perspectives
- http://public.ukcrn.org.uk/ NIHR PORTFOLIO-National portfolio of studies
- https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/262139/Dementia.pdf DH State of the Nation Report

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What's happening in Greater Manchester?

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Current Involvement in Clinical Research for people living with Dementia in Greater Manchester

- 1.3-1.6% population of GM: 2.6 million about **n=33 000 people with dementia**
- Approx **18 000** people have a diagnosis
- **1543 people - 8.5%** currently involved in clinical studies (NIHR portfolio 16.02.15)

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Clinical Trials of Investigational Medicinal Products

- Completed 10 Industry Sponsored clinical trials (Mild to moderate AD/Parkinson's Disease Dementia)-Phase IIa/IIb and Phase III
- Ongoing….
  - Roche Phase III study-mild AD
  - Merck 017 Phase II/III- Mild –Moderate AD and Merck 019 Phase III MCI (prodromal AD)
- About to start……
  - Phase II patients with agitation
  - Phase III in mild to moderate AD
  - Phase II moderate stage AD

Grant- and Investigator-funded Clinical Trials				
	GREAT: Cognitive Rehabilitation in dementia	Mild Dementia	2013-16	CI: Linda Clare (Bangor)
	iCST: Cognitive Stimulation in dementia	Dementia	2012-13	CI: Martin Orrell (UCL)
	Brain Training with rTMS (Neuronix)	MCI	2012-13	CI: K.Herholz (UoM)
	ATTILA: Assistive Technology in dementia	Dementia	2013-16	CI: Rob Howard (KCL)
	MARQUE-Agitation and effects on QoL in patients in care home settings	Advanced Dementia	2012-2018	CI: G Livingston (UCL)
	SAMS-Semi-passive, un-obtrusive computer software to detect changes in daily computer use (emails etc) in elderly users over 12 month period	MCI Mild-Moderate AD	2012-2018	CI: I Leroi, A Burns (UoM) P Sawyer, A Sutcliffe (Lancaster) C Ballard
	DAPA-Physical activity programmes for community dwelling people	Mild-Moderate Dementia	2012-2015	CI: S Lamb (Warwick)
	RfPB PDD -iCST	Parkinson's Disease Dementia	2015-2017	CI: I Leroi (UoM)

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NHS National Institute for Health Research

Home | About the service | How it works | Why sign up? | Any questions? | For professionals

Welcome to 'Join dementia research', a place to register your interest in participating in dementia research.

Anyone, with or without dementia, can register as a volunteer. Signing up is the first step in becoming involved, supporting vital research studies across the country.

The service is currently being tested, and only includes research studies from the North London area, Essex, Hertfordshire and Luton. However, we will soon invite everyone to register as studies from across the country will be added over the next six months, and some studies will consider volunteers from further afield.

What's new

Your stories

SIGN UP TODAY

> Sign up

> Sign up for someone else

If you already have an account please login.

Key things you should know about the service

- Sign up today
- Answer as many of the questions as you can
- View the studies you match to
- Share this page and encourage your friends and family to sign up
- Visit the website regularly to see your study