UNIVERSITY OF BIRMINGHAM

KING'S College LONDON

Ethical considerations when undertaking research with vulnerable populations: Insights from research in mental health, substance misuse and homelessness

Professor Vibhu Paudyal

University of Birmingham

Professor Appointee- Kings College London

Fellow of European Society of Clinical Pharmacy

University of Birmingham MDS global health travel awards

Est 1900 AD

39,000 students

9000 staff

World Top 100 University- US News and World report

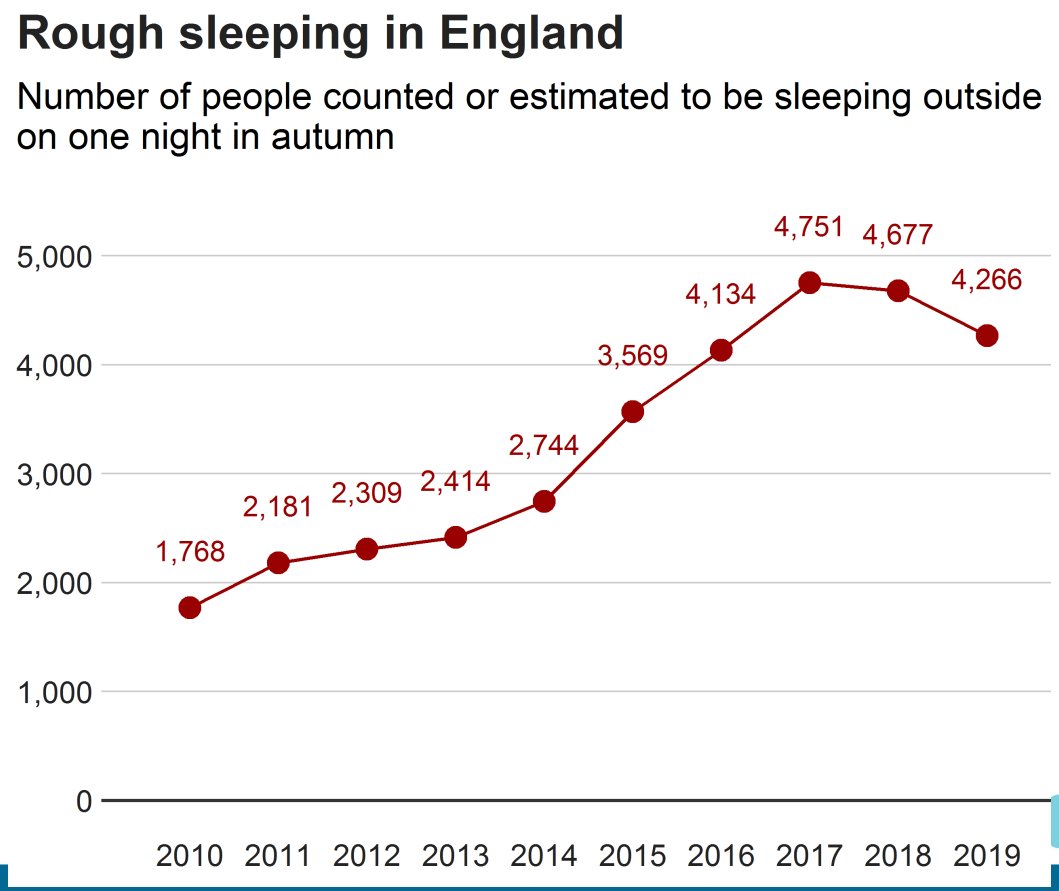
Homelessness

- Rooflessness (without a shelter of any kind, sleeping rough)
- Houselessness (with a place to sleep but temporary, in institutions or a shelter)
- Living in insecure housing (threatened with severe exclusion due to eviction, domestic violence, or ‘sofa surfing’)

Gov.UK

Homelessness trends

In any given night, approximately 700,000 persons in Europe are known sleep rough or spend the night in emergency/temporary accommodation- 70% increase in ten years



Mortality, mental health and suicide

Mean age at death of homeless persons in the UK is 45.9 years for males and 43.4 years females, 40% of deaths caused by poisoning. Suicides increased by 30% in one year

(Office of National Statistics)

PHOENIx Community Pharmacy Trial design

We hypothesised that a pilot randomised controlled trial of outreach by prescriber pharmacists + homelessness support workers, achieves progression criteria and may improve health outcomes (Physical health, mental health, addiction, rough sleeping)

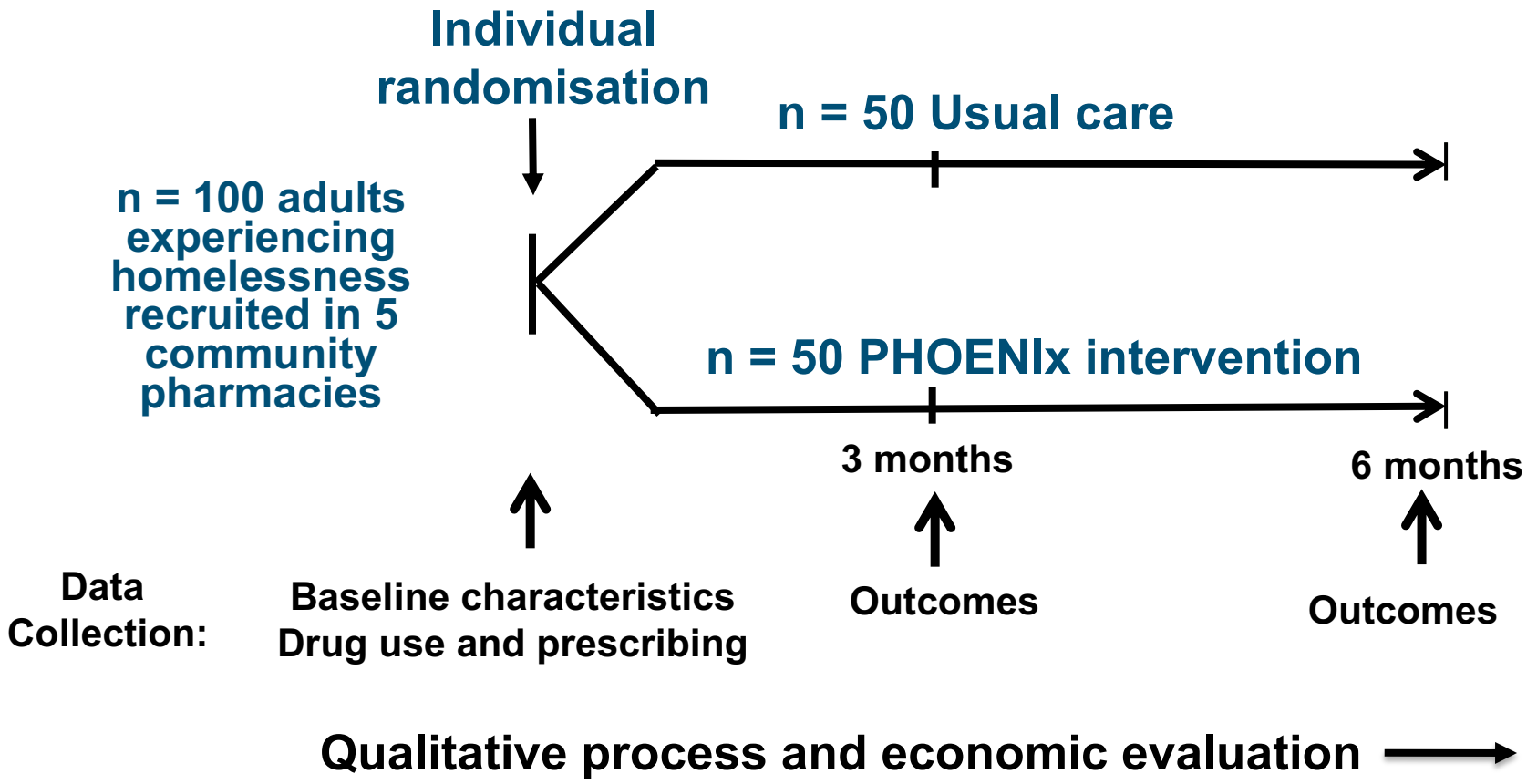
PHOENIx Intervention Components

- Pharmacists clinically assess participants for a range of physical, mental health and drug and alcohol related problems and prescribe and refer based on clinical needs and patient priorities. Pharmacists work closely and collaboratively with General Practitioners (Family Medicine) and other community based multidisciplinary teams.

- Third sector worker offer housing advice, social prescribing, welfare benefits assessment, debt counselling, and criminal justice liaison.

https://fundingawards.nihr.ac.uk/award/NIHR133060

Trial profile



Outcomes

- Primary outcomes are patient recruitment, retention, follow up, intervention adherence and the extent to which outcomes data on emergency department (ED) visits and mortality could be collected in preparation for a definitive RCT.

- Secondary outcome: ED visits, mortality, hospitalisation, quality of life; addiction measures and social measures such as housing tenure.

Informed consent

- A process by which a subject voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form..

- Three key elements: Adequate information, voluntariness, Capacity

ICH, GCP E6 1.28

Capacity to consent

Assessment based on whether a person is able to:

- Understand, evaluate and retain (for as long needed…) the information to be able to make a decision
- Communicate their decision/teach back
- Simple questions, ‘what is the date today?’
- Capacity can depend on the complexity of the information provided, method to communicate, setting in which the information is conveyed…
- Impact of emotional state (e.g. grieving), and physical health

Avoid group specific attribution of (lack of) capacity*

- E.g. not everyone with schizophrenia are the same, not everyone under the influence of alcohol/substance lack capacity
- Lack of capacity can be partial or temporary

Inclusion of subjects who lack capacity

- The possible inclusion of subjects who lack capacity to consent in a study should be specifically mentioned in the research proposal and this proposal should be reviewed by a research ethics committee

Research and consent with adults lacking capacity

Reasons for inclusion of persons lacking capacity	Proxy methods used
■ Must have specific reasons for inclusion ■ Direct benefit outweighs foreseeable risk ■ Research must be about the person's condition or treatment ■ Benefit vs burden/risk assessment	■ Personal legal representative e.g. family member ■ Professional legal representative- e.g. a doctor not involved in the study Or nominated third party (e.g. lasting power of attorney) ■ Nominated consultee e.g. mental health advocate

Hardicre 2014

Protecting subject rights

- *Their best interests be protected…not exploited…but not discriminated against in terms of advancing their treatment and care*
  - Labuzetta et al 2011

Proxy consents

- What would be the person's choice if they had the capacity?
- What will be in the best interests of the person?
- *Implied consent* (e.g. A person had capacity and offered consent but now lacks it)
  - The Mental Capacity Act (2005) England and Wales
  - Medicines for Human Use (Clinical Trials) Amendment no. 2 Regulations (2006) 2006/2984

Deferred consent

- Consent after the intervention has begun
- Research related to life threatening conditions
- If possible, obtain consent after the person has regained capacity/ consciousness
- Rarely used

Further considerations for researchers

- Rapport, relationship key
- Make connections- talk about football, make a connection, speak to family/carers, support workers, *how was the day?*
- Dress, attire of the researcher, flashy laptop?
- Time constraints: e.g. if participants are experiencing homeless, drug users, they might not have lot of time- other priorities e.g. to gather food, beg, to sit; vouchers, food parcels can be helpful
- Keep information short and factual- Abbreviated consent forms- ethics committees may have diverse views

Further consideration for researchers

- Time of the day, e.g. just after methadone
- Recruitment through charity hub, trusted partners
- Large fonts, voice amplifier where needed
- People may feel embarrassed to tell they cannot read or write
- Important to have all means to follow up in the consent form…*I will try and find you, it is my job and not your job, but need your consent to do so…*

Researcher safety and wellbeing

- Persevere- do not take personally if participants may bring something negative
- Lone working policy
- Dynamic risk assessment- maintain your safe space, what you would do if a participant goes violent and aggressive, make excuses to leave, avoid sharing lifts, use open spaces
- Needle risks- soft furnishings, sleeping bags…

Acknowledgements

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