GIG CYMRU NHS WALES

Iechyd Cyhoeddus Cymru

Public Health Wales

The PROTECT study; a feasibility trial of a psychosocial intervention to reduce blood borne virus (BBV) risk

A three country collaboration led by the National Addiction Centre, Kings College London

Funded by NIHR; Health Technology Assessment

The research team and research sites

London

- King's College London: Dr Gail Gilchrist (CI), Davina Swan, Prof John Strang

York

- University of York (trials unit): Dr Ada Keding, Dr Steve Parrott, Dr Judith Watson

North Wales

- Betsi Cadwaladr University Health Board
  Sarah Towers
- Public Health Wales
  Dr Noel Craine

Glasgow

- University of the West of Scotland: April Shaw, Dr Alison Munro, Prof Avril Taylor

Background

In the UK amongst people who inject drugs 23%-61% are hepatitis C positive. Recent outbreak of HIV

UK surveillance reports sharing of needles in the previous month at 16% of individuals attending drug treatment services

Opiate substitution therapy and needle exchanges have reduced HIV and HCV

Whilst HCV treatment is greatly improving it is very expensive and treating patients challenging

Reducing BBV among people who inject drugs **remains a public health priority**

Rationale

- **Psychosocial interventions** (such as motivational interviewing, cognitive behavioural therapy and contingency management) could potentially further decrease BBVs by educating drug injectors about transmission risks and developing strategies to avoid them

Aims

- to **understand influences** on BBV risk behaviours
- to **develop an evidence-based psychosocial intervention** aimed at reducing transmission risk and increasing knowledge
- to **explore the feasibility of recruiting to a trial** comparing the intervention to control
- to **explore the feasibility and acceptability of a psychosocial intervention**

Systematic review to describe evidence base for what works to reduce BBV risk

Qualitative work to determine experience and views of patients and professionals

Development of psychosocial intervention

Feasibility trial

Follow up with patients and intervention providers

How was the intervention developed?

Evidence

Qualitative research

Expert opinion including peer group involvement

The intervention development group

Developed by:

Research Team

Gail Gilchrist, John Strang, Davina Swan (King's College London); Alison Munro, April Shaw, Avril Taylor (University of the West of Scotland); Noel Craine (Public Health Wales), Sarah Towers (Betsi Cadwaladr University Health Board); Liz Hughes (University of Huddersfield).

Intervention development group (in alphabetical order)

Stephanie Brickwood (Wrexham Addiction Recovery Meeting); Archie Christian (The Hepatitis C Trust); Jon Derricott (Film Maker); John Dillon (University of Dundee); Paul Donachy (Scottish Drugs Forum); Magdalena Harris (London School of Hygiene and Tropical Medicine); Paul Lennon (Aurora Project); Martin McCusker (Lambeth Service User Council); Luke Mitcheson (South London and the Maudsley NHS Foundation Trust); Danny Morris (Drug Training & Consultancy); Terry Shields (South London and the Maudsley NHS Foundation Trust); Josie Smith (Public Health Wales); Carla Treloar (University of New South Wales); Jason Wallace (Scottish Drugs Forum)

What emerged from the preparatory phase?

From the systematic review

Addressing “symbiotic ” goals such as avoiding injecting related scars and maintaining venous access, may result in the use of sterile injecting equipment

Include protective practices and strategies to avoid injecting risk situations such as withdrawal and lack of preparedness

From interviews with 60 drug injectors

- **Interplay of structural, situational and individual factors influenced injecting risk behaviours**
  - Drug-related states
  - Trajectory of Drug Use
  - Relationships and social networks
  - Access to resources/ lack of preparedness
  - Values, mental health and life events
- Interventions should **target other injecting-related priorities** including improving injecting techniques and venous care to promote the use of sterile injecting equipment, and **protective strategies to avoid risk**

The PROTECT Intervention

The PROTECT intervention (3 x 1 hr sessions)

1. **Session 1**
   - Improving injecting techniques, good vein care
2. **Session 2**
   - Planning for risk situations
3. **Session 3**
   - Understanding BBV transmission risks

- Sessions used videos, games and exercises to facilitate discussion and build skills and strategies to reduce and avoid risk.
- All sessions also included a didactic education section.
- Separate groups were held for women and men.

SESSION 2: PLANNING FOR RISK SITUATIONS

Goals for Session 2:

1. Identify situations where injection and sexual risk behaviours more likely.
2. Identify barriers to reducing injection and sexual risk behaviours.
3. Identify solutions for reducing injection and sexual risk behaviours.
4. Plan for avoiding situations where injection and sexual risk behaviours more likely.
5. Motivate participants to plan for risk situations.

Objectives.
Participants will:

- increase their awareness of situations where injection and sexual risk behaviours may be more likely.
- understand why in certain situations some people who inject may engage in injection and sexual risk behaviours.
- be able to identify and provide solutions to injection and sexual risk behaviours.
- use the TALK model to negotiate safer injecting and sexual practices.
- develop a "be prepared" plan for risk situations.

Session 2 outline:

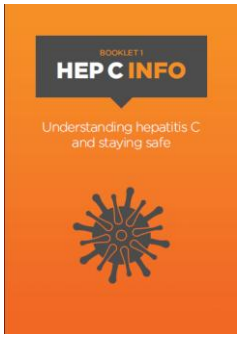
2.1 Welcome and feedback on Session 1 (5 minutes)
2.2 Why do people do risky things that can put them at risk of blood borne viruses? (20 minutes)
2.3 Skills Building: Using TALK to Negotiate Safer Sex and Injection Behaviours (15 minutes)
2.4 Developing a "be prepared" plan for risk situations (20 minutes)
2.5 Review and close

The feasibility trial

After baseline assessment study participants randomised to:

Treatment group

PROTECT 3 x 1 hr sessions of psychosocial intervention plus Hep C Info booklet & leaflet about HIV outbreak



Control group

Hep C Info booklet & leaflet about HIV outbreak only

Both groups also received treatment as usual and were incentivised financially/vouchers

176 eligible patients recruited at baseline (males and females)

Measuring any potential impact

Recruitment and retention in the trial

Surrogate self reported markers of risk, knowledge, self efficacy and health related quality of life

Economic assessment of health and social resource used

Feasibility trial outcomes

- Fewer reported injecting risk practices, self-efficacy, better hepatitis C and B transmission knowledge and greater use of withdrawal prevention techniques

- At one month post-intervention follow up: Intervention did not appear to encourage riskier injecting practices or increase frequency of injecting

- Acceptable to staff and patients

Feasibility

- 56% (99/176) of eligible participants were randomised into the feasibility trial
- 38% (20/52) on intervention arm attended at least one session
- Men were more likely to attend at least one intervention session than women
- Attendance to at least one intervention session was highest in London (63%) and North Wales (54%), whereas only 25% attended in Glasgow, and no participants attended in York.

Results

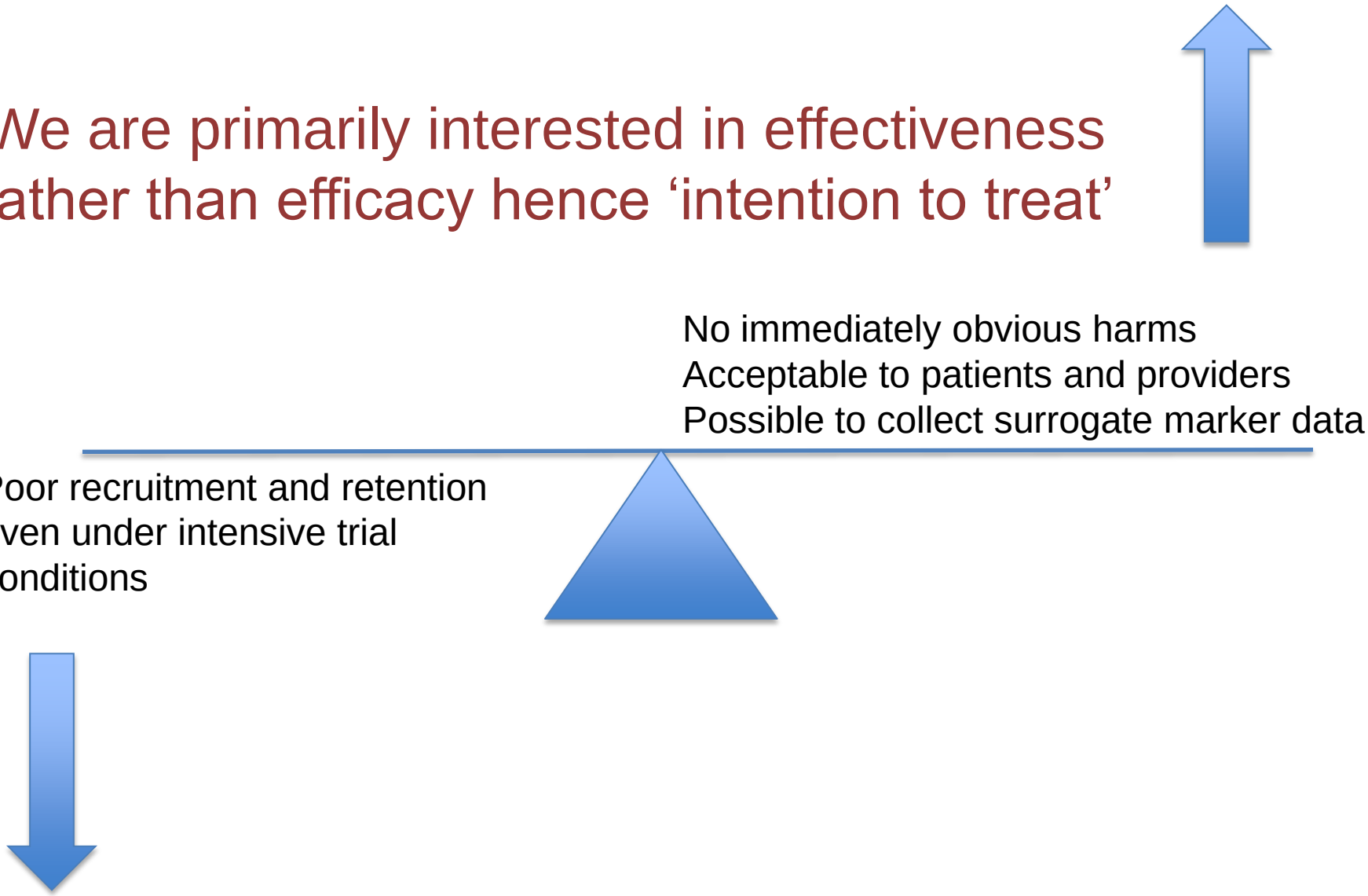
Those who did **not** attend any sessions were more likely to

- Be homeless
- Have injected on a greater number of days in the last month
- Used a greater number of needles from a Needle Exchange in the last month

Estimated mean cost per participant was £270.67 for those attending all three sessions, compared to £0.86

Progress to full trial

We are primarily interested in effectiveness rather than efficacy hence ‘intention to treat’



Full trial not justified

Progress to full trial

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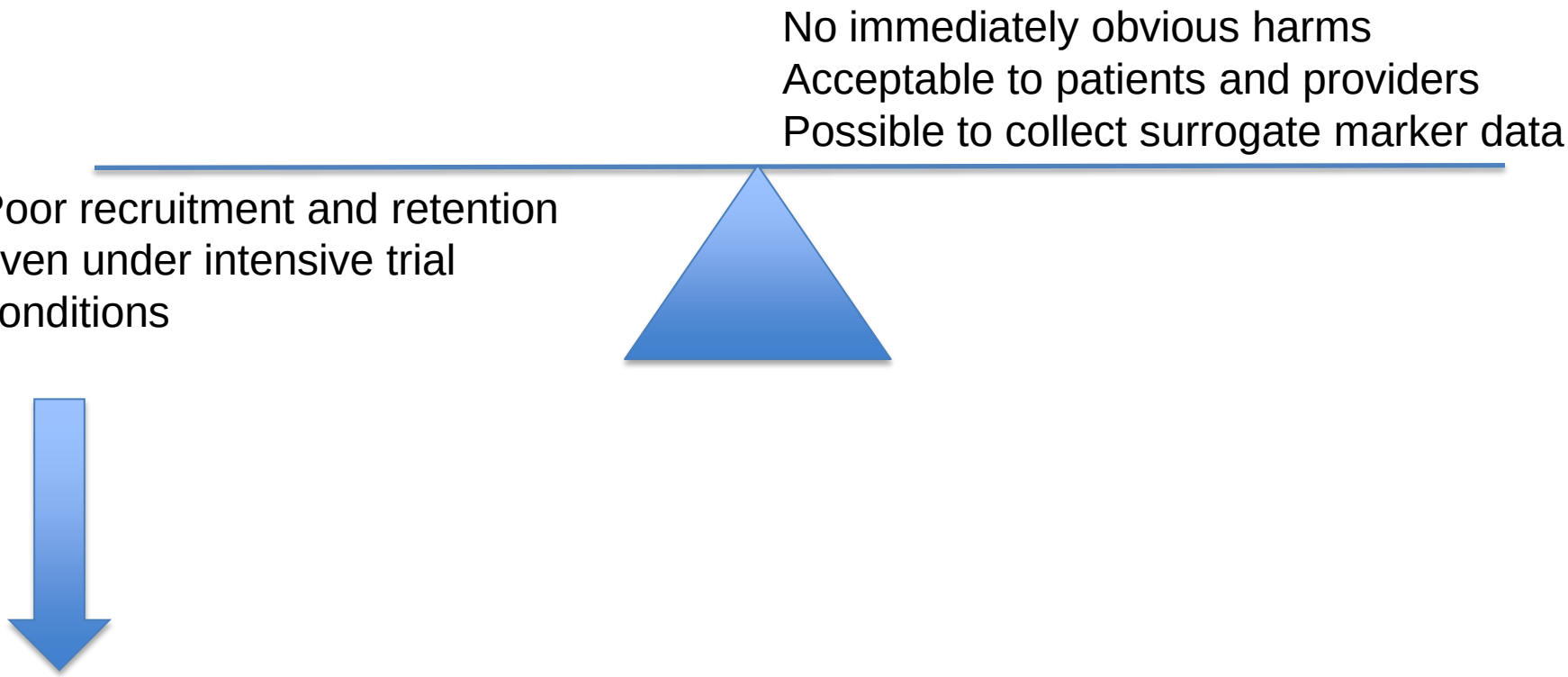

Full trial not currently justified

Why this cautious and rather disappointing conclusion?

Structured interventions of this nature require considerable resources that could be directed at interventions with a more robust evidence base

There is an opportunity cost to most (or all) of our public health interventions

Reasons to cautious

Ioannidis J.P. **Contradiction and initially stronger effects not unusual in highly cited research on clinical interventions**. JAMA 2005; 294(2): 218-228

49 highly cited clinical studies (in NEJM, JAMA, Lancet)
45 claimed effectiveness

- 16% contradicted
- 16% effects weakened
- 44% replicated
- 24% unchallenged

Non-randomised more likely to be contradicted

Among randomised smaller trails – more likely contradicted

What now?

The intervention was prepared with consultation and considerable peer and expert involvement – and it was acceptable and is freely available for use and may support existing educational intervention initiatives

Clearly there were differing barriers to implementation across the UK; unless these are understood intervention effectiveness is likely to be compromised

There is a need for a greater embedding of BBV risk reduction in the work of substance use services / needle exchanges

RCTs have an important role in development of public health interventions

Download the PROTECT intervention

https://www.kcl.ac.uk/ioppn/depts/addictions/research/drugs/PROTECT-download-page-form.aspx