Evaluating the health effects of social interventions

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Is no evidence better than any evidence when controlled studies are unethical?

Rigorous evidence on the health effects of social interventions is scarce. Despite calls for more evidence from randomised studies, one reason for the lack of such experimental research on social interventions may be the perception among researchers, policymakers, and others that randomised designs belong to the field of experimental research on social interventions. Such experimental research on social interventions may be problematic but is not always impossible and is a desirable alternative to uncontrolled experimentation. However, even when randomised designs have been used to evaluate social interventions, opportunities to incorporate health measures have often been missed. For example, income supplementation is thought to be a key part of reducing health inequalities, but rigorous evidence to support this is lacking because most randomised controlled trials of income supplementation have not included health measures. Current moves to increase uptake of benefits offer new opportunities to establish the effects of income supplements on health. In attempting to design such a study, however, we found that randomised or other controlled trials were

Summary points
Antiretroviral therapy is becoming more affordable for developing countries
Infrastructure is also essential to deliver the complex and sensitive drug regimen
DOTS has been suggested as a method for delivering antiretroviral therapy, although it has limited success for tuberculosis in much of Africa
Suboptimal adherence to antiretroviral therapy is likely to result in the transmission of drug-resistant virus strains within the community
Other methods for ensuring adherence need to be developed and evaluated

prescribing practices and poor monitoring of therapy and adherence.

A rational approach is required in which system delivery and proved methods for maximising adherence are as important as procuring the drugs themselves. This should be led by a respected international organisation that has the objectives of overcoming short term suffering as well as preventing a similar disaster in the long run, by insisting that antiretroviral policies incorporate a phase of piloting systems that seek to maximise adherence.

Contributors and sources: WS has worked with the World Bank in predicting the effect of HIV in West Africa, and with the Department for International Development and the London School of Hygiene and Tropical Medicine on the economics of tuberculosis control programmes. SK has worked on monitoring HIV drug resistance in trials of antiretroviral therapy conducted in the United Kingdom and Europe. TC has been in charge of the clinical services provided by the MRC unit in the Gambia since 1986 and has specialised in the care and treatment of patients infected with HIV and tuberculosis.

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19 Orrell C, Bangsberg DR, Badri M, Wood R. Adherence is not a barrier to successful antiretroviral therapy in South Africa. AIDS 2003;17:1369-75. (Accepted 1 December 2003).
A pilot study carried out by one of us (RH) showed substantial health gains among elderly people after receipt of attendance allowance. We therefore decided to pursue a full scale study of the health effects of income supplementation. The research team comprised a multidisciplinary group of academics and a representative from the Benefits Agency (TQ). Our aim was to construct a robust experimental or quasi-experimental design (in which a control group is included but not randomly allocated) that would be sensitive enough to measure the health and social effects of an attendance allowance award on frail, elderly recipients.

The intervention

The intervention involved a primary care based programme that aimed to increase uptake of benefits. In 2001, community nurses, attached to a general practice serving the unhealthiest parliamentary constituency in the United Kingdom, screened their frail elderly clients for unclaimed attendance allowance (box 1). Potential underclaimants were then visited by a welfare rights officer, who carried out a benefit assessment, and the claim was then forwarded to the Benefits Agency (part of the Department of Social Security) for the final adjudication of applications (figure). This resulted in 41 clients receiving additional benefit totaling £112 892 (€160 307; $200 302), with monthly incomes increasing by £163-£243.

Outcomes

We chose change in health status measured by the SF-36 questionnaire as the main outcome variable. Explanatory variables, which recipients had linked to increased income in pilot interviews, were also incorporated. These included diet, stress levels, levels of social participation, and access to services. We intended to assess health status before receipt of the benefit and at six and 12 months afterwards. An economic evaluation was also planned.

Study design

We initially considered a randomised controlled trial. However, we encountered problems with the key elements of this design. The study designs considered and the issues raised are outlined below.

**Design 1: randomisation of the intervention**

Under a randomised controlled design successful claimants would be randomised immediately after the adjudication decision by the benefits agency. Those in the control group would have their benefit delayed by one year, and those in the intervention group would receive the benefit immediately. This design would ensure that the health status and benefit eligibility of both groups were comparable at baseline. However, the research group considered this design unethical because of the deliberate withholding of an economic benefit, which would also be unacceptable to participants. This design was therefore abandoned.

**Design 2: randomising to waiting list**

The introduction of a three month waiting list between initial assessment by a nurse and assessment by the welfare rights officer provided an opportunity for random allocation to the control and intervention group. We obtained approval to randomise the clients to a waiting list of a maximum of three months from the Benefits Agency, which provides the welfare rights officer. Thus, elderly clients referred by the nurse to the welfare rights officer could have been randomised to receive the visit either immediately (the intervention group) or after three months (the control group). This design would have allowed us to compare the groups at the desired time points and provided a directly comparable control group in terms of health

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**Box 1 Attendance allowance**

- Attendance allowance is payable to people aged 65 or older who need frequent help or supervision and whose need has existed for at least six months
- The rate payable depends on whether they need help at home or only when going out and whether they need help during the day or the evening, or both
status and benefit eligibility. However, it randomises
the benefit assessment and not the intervention of
interest (receipt of the benefit), and a delay of three
months would probably not be long enough to detect
important health differences between the two groups.
More importantly, it is unlikely to be ethically
acceptable to request that study participants, already
assessed to be in need of an economic benefit, accept a
50% chance of delaying the application process for
three months in the interests of research. We therefore
rejected this design.

Design 3: non-randomised controlled trial
A third potential design entailed identifying a
non-randomised control group from a nearby area
with a similar sociodemographic composition but with
no welfare rights officers. In this design, community
nurses would have screened potential underclaimants
in the control area, who would then have been offered
a standard leaflet on how to apply for attendance
allowance (a nominal intervention corresponding to
“usual care”). This design would have eliminated some
of the ethical concerns associated with randomisation
and delaying the receipt of benefit, and would have
achieved an intermediate level of internal validity by
retaining a comparison with a control group. However,
recruitment and retention of this control group raises
problems.

The success of this design depends on participants
in the control group delaying their claim for the dura-
tion of the study. Although the effectiveness of the
“usual care” intervention, the leaflet, is normally poor,
we considered it unlikely that this would be the case
after assessment for the study as participants are made
aware of their potential eligibility for the benefit. We
thought it unacceptable to request that participants
delay claiming the additional benefit after drawing
attention to their eligibility.

Design 4: uncontrolled study
A before and after study of a group of benefit
recipients would be more ethically acceptable, but it
would be more difficult to attribute any observed
change in health status to the intervention alone.
We applied for research funding for a study based on
this design, citing the practical and ethical difficulties in
designing a randomised controlled trial, but the appli-
cation was rejected mainly because of the lack of a con-
trol group. We presume that the underlying assump-
tion was that such an uncontrolled study would be so
biased as to provide no useful information.

Discussion
Our initial aim was to design a randomised or controlled
study to detect the health effects of income supplemen-
tation. Our failure to design such a study and to get
funding for a less rigorous study poses the question of
what sort of evidence is acceptable in such situations.
Social interventions differ from clinical and most
complex public health interventions in that changes in
health are often an indirect effect rather than a primary
aim of the intervention. Investigation of indirect health
effects often requires choices to be made between com-
peting values, usually health and social justice, creating a
moral problem. When, as in our study, the tangible social
and economic gains generated by the social interven-

Summary points
The health effects of social interventions have
rarely been assessed and are poorly understood
Studies are required to identify the possible
positive or negative health impacts and the
mechanisms for these health impacts
The assessment of indirect health effects of social
interventions draws attention to competing values
of health and social justice
Randomisation of a social intervention may be
possible using natural delays, but adding delays
for the sole purpose of health research is often
unethical
When randomised or other controlled studies are
date not ethically possible, uncontrolled studies may
have to be regarded as good enough

tions outweigh the theoretical possibility of marginal
health effects, the moral issues are clear.

Randomisation
Although judgments about equipoise have recently
been challenged, equipoise around the primary cli-
cial outcome has been the ethical justification for
randomising clinical interventions.10 11 12 13 14 Equipoise
implies uncertainty around the distribution of costs
and benefits between two interventions. Designing a
randomised study may be simple in theory, but in cases
where the equipoise is around uncertain indirect
health impacts, and the primary economic or social
impacts seem certain, true equipoise is unlikely and
randomisation may be unethical.

Randomising a control group need not always
present ethical hurdles. There may be inherent delays in
rolling out a new or reformed programme across an
area, or an intervention may require rationing or be sub-
ject to long waiting lists. These delays may provide ethi-
cal and pragmatic opportunities for randomisation12; indeed, randomisation may be the fairest means of
rationing an intervention.13 However, delaying access to
a tangible benefit for individuals who are assessed as “in
need” may not be justifiable on research grounds.

Generating evidence for healthy public policy
An urgent need remains for studies of the indirect
health effects of social interventions to improve our
understanding of the mechanisms by which health
effects can be achieved.15 Attention has already been
drawn to the need for careful design of evaluations of
complex public health interventions,16 17 but guidance
for evaluating the indirect health impacts of social
interventions may require further consideration in
light of the issues outlined above. For example, when
the direct effects are obvious, randomised controlled
trials may be unnecessary and inappropriate.18 In
health technology assessment, other study designs
have an important role in development19 20 and in
helping to detect secondary effects.21 For example, new
drugs with established pharmacological mechanisms

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are investigated at increasing levels of internal and external validity before being tested in a population level randomised controlled trial. Phase I and II studies are often small and uncontrolled, but they help to establish positive and negative effects, clarify the dose-response relations, and provide the background for larger trials.18 In addition, once approved, drugs are closely monitored at a population level to detect previously unidentified secondary adverse effects that may outweigh the primary positive effects.19 Our pilot study was similar to a phase II study.

This matching of study designs to the level of development and knowledge of the effects of an intervention could be usefully applied to the study of social interventions. Non-randomised and uncontrolled studies could be used to shed light on the nature and possible size of health effects in practice, to illustrate mechanisms, and to establish plausible outcomes.18 Such studies may serve as a precursor to experimental studies when these are ethically justifiable and appropriate. However, when randomised studies are not possible, we may have to accept data from uncontrolled studies as good enough, given the huge gaps in our knowledge.19 We need to reconsider what sort of evidence is required, how this should be assembled and for what purpose, and the trade offs between bias and utility so that study designs that are acceptable to research participants, users, and funders can be agreed.

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Contributors and sources: The initial idea for this study was developed by RH. All authors regularly attended and contributed to meetings of the study team, development of the research proposal, and writing the paper. HT, MP, and DO work on a research programme that evaluates the health impacts of social interventions. RH, GL, and TQ worked on initial pilot work investigating Attendance Allowance uptake and its health impacts. NC is a lecturer in health economics and has an active research interest in designing economic evaluations of social welfare interventions.

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Two memorable patients

Two nil

It is a dull wet Saturday afternoon in Goodison Park. The fans are filing in, and there is a tense excited atmosphere around the ground. It is nearing the end of the season, and everyone is hoping the seemingly inevitable relegation battle can be avoided this year. The Goodison faithful are buzzing with the prospect of taking three points from fellow strugglers. Behind the scenes, the usual band of St John Ambulance volunteers have gathered—doctors, nurses, firemen, policemen, dockers, students, and others from all walks of life.

As the match enters the last five minutes, the only thought echoing around the ground is how to put the ball into the goal. Until, that is, a simple radio message is received: “Code Blue, cardiac arrest.”

Just as we all relax, lightning strikes twice: “Code Blue, cardiac arrest in the Gwladys Street stand.” Half our team go tearing off to the second incident, with the match now in injury time. A second unresponsive man is found in cardiac arrest, but not for long. We are joined by an ambulance service team and soon once more have a spontaneous output.

The crowd are now filing out, blissfully unaware as two paramedic vehicles arrive. The first man has spat out his endotracheal tube and is conscious, asking what the score is. Two paramedics arrive with oxygen and an automatic defibrillator. The casualty is in ventricular fibrillation, our team and the club doctor arrive with oxygen and an endotracheal tube. The casualty is intubated and cannulated him, as slick as any hospital operating theatre.

Rotation

Joanne Banks orthopaedic specialist registrar, Mersey Deanery