

Editorial

The challenge of optimising research participation: paying participants in mental health settings

Introduction

There is evidence that research participation rates have been falling in recent years (1). As a result, paying people to be involved in healthcare research is now commonplace and has been found to be effective in encouraging participation and retention (2,3). Paying participants or offering an inducement also ensures that participants benefit immediately, particularly if the outcomes are not perceived as being of any direct benefit. Inducement appears to be a quick and easy solution to the problem of falling participation rates, particularly as the additional cost can be offset by a reduction in the time it takes to recruit or follow-up participants. Further, as technology develops at an increasing pace, researchers will need to recruit quickly and efficiently (4). However, paying research participants remains contentious (5), particularly when involving vulnerable groups such as people with a serious mental illness (6). Surprisingly, the issue of offering research incentives to people with schizophrenia has been largely ignored (7). Some researchers are believed to only offer money to well participants but not to patients (4). Ultimately, many studies involve incentives, with some offering substantial amounts of money to encourage people to become research participants (8,9).

Implications for participants

As payment for participation of vulnerable groups can be exploitative, the amount and distribution should be carefully assessed (10). One problem, particularly with high levels of payment, is the possibility that a person will ignore the potential risks involved in a study and participate when they would not have done so if there was less or no payment offered. Risks include physical,

emotional or psychological consequences of participation, some aspects of which may be long term or unforeseen. The person ignoring such potential risks or overcoming moral qualms by agreeing to participate for payment is deemed to have acceded to undue inducement. That is, undue inducement contravenes respect for individuals, may work against their interest and may involve withheld information and result in inaccurate data.

Undue inducement differs from coercion but involves a desirable incentive that is irresistible and induces decision making against the person's interests. In other words, it is harmful (3,11). Ethics Review committees do not approve studies that use coercion to recruit research participants, yet they do approve studies that offer incentives, either monetary or payment in kind (2,8). Such committees may merely consider the ratio of risks to benefits, with the potential knowledge sought by the trial unlikely to benefit any individual participant (12).

In research involving patients with a severe mental illness, these potential problems are intensified by the possibility that patients may not understand either the consent process or the diverse implications of participation (2,13,14). Many patients with severe mental illness experience difficulties with delusions and thought disorder as well as cognitive functions such as decision making, memory recall and attention (15,16), so they may not always be able to give accurate responses. These patients, however, should not necessarily be prevented from taking part in research, if they wish, as this may increase stigmatisation and limit research to those who have milder or less severe illnesses (2). Determining a patient's capacity to consent and provide reasonably accurate responses may be necessary through pre-consent assessment for these patients (17).

Therapeutic misconception – that is, patients' belief that their participation will result in better treatment – is common and involves patients not understanding important differences between the research conditions and the routine care (2,5,15). Some patients may incorrectly believe that they will directly benefit therapeutically from participating, a belief enhanced if the treating clinician is also the researcher (2,4).

Recent research has shown that people with schizophrenia generally do take into consideration the risks involved when deciding whether or not to participate in research (18). However, they report being more influenced by monetary incentives than by their doctors or family, particularly in apparently low-risk research (5,19). As the amount of payment increases, they are more likely to ignore higher levels of risks (7). This is sometimes, but not always, the case with patients without a mental illness (7,20,21).

Implications for research

Offering low levels of payment over and above minor expenses incurred may encourage more participants from disadvantaged demographics to be recruited, resulting in a biased sample (20). This is a concern for several reasons. First, disadvantaged populations would bear a larger share of the risks and burdens of participation and second, disproportionate distribution of any group diminishes generalisability, threatening external validity (4,5). This argument has been used to endorse higher levels of research payment to attract a more equal distribution across socioeconomic groups (11), although offering no payment at all and relying on volunteers may also ensure a more equal distribution across groups.

The generalisability of research depends largely on whether the research results are free from bias. Those who are motivated to participate by receiving payments may be intrinsically different to those who are motivated to participate for other reasons (22). If a patient agrees to participate for financial reasons, they may not be as diligent as others in giving accurate responses. On the other hand, they may be more diligent, thinking to themselves 'I'm being paid for this, I better give it my best shot'. Even healthy participants have shown differences in responses according to whether they have been paid or not.

Some potential research participants may not reveal information because it does not appear relevant to the study, but which unwittingly may be exclusion criteria (2,3,20). Furthermore, people with limited education may find common research

terms such as placebo and randomisation difficult to grasp and concepts like privacy, treatment and uncertainty may be challenging within some cultures (15,23). Even the right of an individual to give or withhold permission is anathema in societies that honour the group or family first (23).

People with a mental illness may also be at risk of withholding certain information they consider not acceptable to the researcher or irrelevant to the research topic. For example, they may withhold information about activities that may exclude them from or impact on the trial, such as levels of alcohol, tobacco, caffeine and other drug use (2,20). This is especially important, given high levels of concurrent alcohol and other drug use in persons with serious mental illness (24) and the finding that studies of drug-dependent participants are more commonly reimbursed than not (8). The higher the payment offered the more problematic these issues become.

Having a carer involved may limit nondisclosures, particularly of factors that could put the patient at high risk as the carer may want to ensure the patient does not put themselves in such situations. Researchers would need to ensure participants and their relatives fully understand the research and consent processes by spending as much time as necessary explaining these processes. Further, assessments of understanding of these processes may need to be undertaken to ensure a certain level of understanding is achieved (7,11). Where possible and acceptable to patients, the involvement of relatives in studies would assist to validate patient responses and limit any lack of disclosure of restricted activities. Importantly, it may also assist to determine the patient's motivation behind participation.

Remuneration for research participation

Remuneration for research participation commonly includes reimbursement for out-of-pocket expenses such as travel, meals and loss of earnings (2). This is deemed appropriate as it offsets concerns about undue inducement and presents no incentive to conceal information (4,25). However, there is great variety in expenses incurred, as some participants earn more than others, others travel further and standards of living vary (23).

Putting a value on expenses is also difficult – while the opportunity costs, or costs sacrificed by participating in research, are higher for participants who earn more, it could also be argued that they should also be higher for those who value their leisure time more (5). In reality, the amount

differs from study to study and is often dictated by the level of funding, project complexity (26) and the need for expedient recruitment (4). Studies with the highest risk and/or lowest desirability are more likely to have to offer recruitment inducements.

As most research relies on external funding sources, topics may be more or less fashionable depending on public opinion. Fashionable topics often attract funding and are in a position to offer the highest incentives, recruit more participants and are more likely to lead to publications. This in turn increases the ability to successfully secure future funding. Smaller project teams may find it difficult to secure funding and research participants, which may inhibit innovative clinical research. If they are successful in obtaining a small amount of funding, the problem of wisely and fairly spending research funds on research participants is in direct competition with other essential costs such as printing, mail and data entry. There is also a growing expectation among people with a mental illness that they should be paid to participate. Will providing payment upfront reduce a study's ability to retain participants? Providing payments at the end of a trial may reduce drop out rates but may lead to undue inducement to stay. Providing payment periodically on a pro rata basis may alleviate some of these concerns but will increase administration time and costs.

One proposal to standardise payments is to adopt a wage-earner guideline, where all participants are paid at a specified hourly rate with additional payment for uncomfortable or burdensome procedures and not just cover expenses incurred (4,27). Most people would not work without wages, so wages are already an accepted inducement to work. This model should lessen the possibility of exploitation or undue inducement and gives people an opportunity to be paid for work that produces knowledge and contributes to the common good (12). Further, it may be viewed as an indication of respect for participants' effort and time and the contribution they have made (28).

If the wage-earner guideline is adopted, lower profile projects would have to factor in this cost when applying for funding and funding agencies would expect this cost to be included. This would help create a more level funding playing field, enabling projects an equal chance of recruiting participants (25). Admittedly, some projects may still struggle to attract sufficient funding to cover even low payments. In those circumstances, well-paid research may be restricted to highly funded research by drug companies and research centres that benefit financially from the outcome of the research. Smaller projects may still rely on

volunteers who are able to distinguish that the research is being done for the public good (25).

There are other issues to consider with the wage-earner model. If mentally ill participants tend to ignore risks as payment increases (7), they may be more inclined to accept the additional payment for uncomfortable or value-conflicting activities and procedures, particularly if they need the money. Compounding this is the fact that many people with a severe mental illness have limited earning capacity, so they may place more value on any amount of money offered (20).

So what are the alternatives to payment? Some alternatives to paying cash have been offered as a result of concerns about how patients with a mental illness spend their research money. There are concerns about safety, as many patients are homeless and may be at greater risk of robbery if they are carrying large amounts of cash. There are also concerns that they may use the cash inappropriately, such as to buy drugs or alcohol given the high prevalence of substance misuse (8,10,24).

For the above reasons, some studies offer noncash incentives, including items such as food vouchers or goods. Generally, this 'payment in kind' is an item of value equivalent to the amount of money that was deemed appropriate. However, there are problems with offering cash to some research participants and goods to others. Restricting access to cash based on what a person with a mental illness might do with their earnings may be viewed as patronising and discriminatory, and many people in the wider community use their earnings to purchase goods that others consider to be unacceptable (10). Another problem with offering payment in kind is that the goods are of generally the same value as cash, so the issue of undue inducement remains.

Another option is to increase the value society places on participation, not in a monetary sense, but by seeing research participation as a community good or an altruistic act (1). Already, society expects people to assume some risk for the benefit of others (11) and the potential to help others can be an important motivator to encourage participation (29). In many countries, volunteering is valued, but research participation may not normally be understood in this way.

People with schizophrenia often have altruistic attitudes to research (30), particularly those with a higher education (31). Like others, they seek to help society, science and others with the same illness (32). They also seek to foster hope. These motivations can be enhanced if participants feel the potential benefits are likely to materialise and possibly help someone important to them (1).

However, when research is justified ‘as a means of advancing the common good ... there is a moral danger in creating a commodity out of people’s willingness to be research participants’ [London (12), p. 31].

On the other hand, generic advertising campaigns could highlight the value of research participation, providing care is taken not to oversimplify the research or exaggerate its benefits. There have been other similar campaigns, such as those highlighting the worth of donating blood or organs to others (33). Such advertising may be useful to raise awareness that underparticipation may delay or limit the usefulness of study findings (1). A non-partisan body would have to take up such an information campaign, which would need to be well worded and honestly address obvious concerns the general public have about being involved in health or illness research.

Irrespective of the level of payment, we need to ensure research participants feel valued and a useful strategy might be to engage research participants in dialogue to see what makes for a research experience that is rewarding and satisfying (34). Borzekowski et al. (26) recommend that all authors report any payments made to research participants, including the format and the underlying purposes of any such payments, so that the representativeness of respondents and generalisability of results can be assessed.

Finally, an emerging parallel issue pertains to paying researchers engaged in clinical drug trials on a sliding scale, with higher payments for recruiting more patients and following patients to completion. This practice is becoming common in trials presented to Ethics Review Committees. Clearly, it is an inducement to researchers to maximise participation and could result in inappropriate pressure being placed on patients. The issue is beyond the scope of this editorial but warrants separate examination.

Conclusions

Paying people with a mental illness to participate in research is a contentious issue and presently there are no guidelines. High levels of payment may be problematic because of increased risk of undue inducement and concealment of information. It may also be problematic for small projects that cannot afford to pay participants as they cannot compete with those that can, even though a small project may be just as worthwhile. Low payments may increase the likelihood of biased samples, but they also provide a more equitable

platform for participant recruitment. Thus, payment that is neither exploitative nor coercive must be given due consideration (35). The ideal scenario is to encourage participation for altruistic reasons, and more research is needed to investigate whether raising public awareness about the value of broader participation in health research is effective.

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Editorial

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