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الطريقة: تم توزيع التحديات إلى ثلاث مجالات: ما يتعلق بمجموعة الأفراد المعنيين في السلوك والصحة، وما يتعلق ببيئة الخدمات التي يتم فيها إختيار أفراد العينة، وما يتعلق بتصميم الدراسة.

النتائج: التحديات التي تواجه هذه الدراسات تتعلق بسلوك الفوضى والدافعية لدى متعاطي المخدرات، وإرتفاع معدل عدم الإلتزام بالعلاج، بالإضافة إلى جوانب تتعلق ببيئة الخدمات وتعريف هذه المجموعة من المدمنين و إختلاف طرق الإختبار في مراكز الخدمات، وإلى تصميم طريقة البحث والتعويض الذي يدفع للمشاركين و إستخدام العاملين الموظفين بدل الباحثين المتمرسين كمعالجين.

الخلاصة:

الدروس المستفادة كانت واضحة في ضرورة عمل دراسة أوليه رياديه للعلاجات الجديدة، كأمر أساسي قبل الخوض في دراسات مقارنة ضابطه عشوائية للمداخلات النفسية في ميدان الإدمان. كما أن وجود البنية التحتية الثقافية للمداخلات النفسية ضرورية لتنفيذ البحث التطبيقي في بيئة الخدمات، كما أن الدعم المالي ضروري لتوفير المعالجين المؤهلين القادرين على تقديم هذه المداخلات.

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presents challenges that are very different from those encountered in US studies upon which research in addiction is often modelled, as was the case in this project. RCTs in the US are usually conducted against a background of higher funding which facilitate pilot work, the formation of larger research teams, and therapists who are dedicated to the trial rather than relying on service staff trained in delivering the experimental and control interventions. Research in the US also benefits from a well-established clinical research infrastructure, which aids the introduction of new interventions, increasing compliance from staff and users. Indeed, the development and fostering of a culture of research within the services involved in the present trial was a task that had to be instigated. There is also reason to believe that the clinical populations in the US are different to those in the UK, with those engaged in treatment being older, and more socially stable; this is of consequence because it is important that service users are well-engaged in standard drug treatment regimes before introducing further demands such as structured counselling sessions. Another of the lessons learnt is the need for piloting of the new intervention in an area of research that involves the development of new interventions amongst a difficult clinical population, with only limited guidance available from other research.

One of the main policy implications for conducting trials of psychological interventions within addiction health care settings is for funding bodies to provide the necessary resources to improve the quality and comprehensiveness of treatment including the provision psychological interventions. This would provide the necessary infrastructure and capacity for the development of innovative interventions and thus offering opportunities for the evaluation of their effectiveness and costeffectiveness in pragmatic clinical trials

الملخص:

الخلفية: لقد أنهينا دراسة مقارنه عشوائية ضابطه، لفعّالية الإرشاد المحفز الوقائي في الوقاية الأولية من مرض إلتهاب الكبد الوبائي(C) في مستعملي الحقن الذاتي للمخدرات. من خلال الدراسة واجهنا تحديات منعتنا من إيجاد العدد المناسب من المشاركين، وبالتالي لم نتمكن من تحديد فعالية الإرشاد المحفز ا لوقائي في تخفيض الإصابة بإلتهاب الكبد الوبائي(C) بين المدمنين على الحقن الذاتي للمخدرات.

الهدف:وصف التحديات التي تواجه إجراء دراسات مقارنه ضابطه عشوائية للمداخلات النفسية، و البحث الناقد لإنعكاسات ذلك على إجراء مثل هذه الدراسات للمداخلات النفسية في مجال الإدمان.

their discussion is beyond the scope of this paper.

Randomisation in psychological interventions

The RCT has long been the "gold standard" for all types of research, yet it is more problematic for psychological trials than it is for pharmaceutical drug trials. Participants many of whom were ready to address issues of health and risk, and having the motivation to do so, may have been allocated to the control group. Randomisation works both in favour of and against pragmatism; it is not feasible to test an intervention if only those most likely to change are included, as this will likely become a self-fulfilling prophecy. Also in real-world applications, it is unlikely that individuals who are considered by the therapist to be unsuitable for a particular intervention at that time would be encouraged to participate in it. It is difficult to strike a balance between these competing needs, and the randomised controlled trial remains the best method of investigation that we have, despite its drawbacks.

Pragmatic or efficacy trials

A pragmatic trial is one in which the object is to not only test an intervention, but to test it in a reasonably realistic manner that replicates to an extent the conditions under which it is likely to be adopted if it were found to be effective and then introduced more widely. In contrast, an experimental trial is less concerned with practical implementation and more with ensuring that a satisfactory test of an intervention is made. In the traditional model, experimental trials come first, and then their practical application in real-world settings is made. Pragmatic trials attempt to combine both stages into one, and when successful, solve two problems at the same time. When they do not, it is often not possible to disentangle the two stages, such that it remains unclear whether it is the intervention or the specific implementation of it that was at fault, or perhaps both. The research that we carried out was substantially of the pragmatic variety. Pragmatic trials have advantage over efficacy trials as their findings could be generalised and widely implemented in service settings. The research is carried out in real situations, with inclusive criteria, representative populations, and by regular staff. In such situations, a negative finding is just as important as a positive one. In the present study, the close modelling on similar previous research and the inherent face-validity of the new intervention were important aspects of its effectiveness as evaluated in the National Heath Service setting.

Lessons learnt

One of the main lessons learned in this project is that conducting research in UK treatment settings

both CBT and MMT due to high staff turnover and motivational issues; low level of client engagement in CBT.

In discussion, we suggest the following over-arching issues for consideration:

Psychological interventions

The environment from which participants were recruited was not often resourced for the provision and testing of psychological interventions. There was also the legacy of drug addiction services being largely perceived, again by both service users and the services themselves, as primarily in the realm of medical science as opposed to psychological, and focused around the provision of substitute drugs. Service users arrive at services with varying expectations, but for many the availability of substitute drugs and perhaps needle exchange facilities is primary. They do not necessarily anticipate psychological input, and therefore do not desire it or demand it. This is reinforced by lack of resources for providing psychological treatment on the part of services, and a culture that does not lay emphasis on working in this way.

Pilot the intervention

The provision of a pilot study would have helped address many of the problems that we faced when attempting to implement the trial. Indeed, this is the very purpose of any pilot study, yet they are frequently not carried out. In this instance the research team and funding body assumed that it would not be necessary due to the close modelling on other existing research, and the experience of the team in conducting research of this nature. In the context of bidding competitively for available research funding, the ability to deliver a research project at the absolute minimum cost is essential, and it is often most practical to cut down on the piloting aspects of work wherever possible. Although the research succeeded in generating a wide range of useful findings above and beyond those reported in this paper, the inability to prove the primary hypothesis of the project was disappointing, and perhaps could have been avoided if sufficient time and effort was spent prior to the research in investigating aspects that were later found to be troublesome. However, pilot studies are only useful insofar as they mimic the conditions of the actual trial, and the closer they are to the actual conditions, the more useful they become, but also more costly and time consuming. Although our trial may have benefited from being piloted first, it is equally likely that a small-scale limited pilot study would not have identified many of the issues that were found to be problematic in the main trial. The benefits and disadvantages of conducting pilot studies are many, but

consent was fully informed. As such, pre- and post-test counselling sessions were sometimes longer and more involved than the control intervention was, and may have provided sufficient information and understanding such the trial intervention was no longer seemed as necessary as it might have done before. Service users may have felt that they knew all they needed to know for the time being, and declined to take part in the research. Thus, although it was problematic for the research in terms of achieving sufficient numbers and in ensuring adherence to the Trial intervention, it was an unequivocal benefit to the service users that testing was made as widely available and accessible as possible, and that knowledge and awareness of hepatitis C was increased amongst the population.

Discussion

The Trial clearly had several indirect benefits, and several shortcomings. The first positive outcome was the impact of the research on clinical practice, through the introduction of a new method of testing that has continued to be adopted by the services, and the increased knowledge, awareness and understanding of hepatitis C, both for service users and the staff. Secondly, the therapists were trained and accredited in the delivery of a manual-guided intervention that although still unproven in effectiveness, is strongly believed to be useful and is amenable to adaptation and incorporation into the routine therapeutic armamentarium of the service. Thirdly and most importantly that over the three-year period that recruitment for the research was active, the vast majority of those at-risk for contracting hepatitis C were tested and made aware of their HCV status. Moreover those who were HCV negative may well be motivated to remain so, and those who were found to be HCV positive will access the treatment of HCV infection. The shortcomings and problems encountered during the trial have informed the research team, the clinical teams, and others of the difficulties of conducting research in addictions.

Similar difficulties were encountered in conducting the UK RCT [11] on the effectiveness and cost effectiveness of cognitive behaviour therapy (CBT) for opiate misusers in methadone maintenance treatment (MMT): Low baseline levels of CBT trained staff; low rates of subject eligibility and willingness to participate, particularly in certain sites; poor engagement in, and drop out from, standard methadone treatment; delay in obtaining treatment costs for the trial interventions; high turnover of staff; delays in therapists obtaining training accreditation; attrition of therapists in

work priority preferring to attend to their clients treatment needs probable arising the dynamics of the service, and in the context of performing multiple roles in a demanding service with a difficult client group. Motivation was a larger issue as time went on, as recruitment to the trial was first delayed due to factors out of our control, and then much slower than expected when it began. Hence, intrinsic goodwill and motivation that was abundant at the beginning of the trial was diminished as time went by and the therapists sometimes faced weeks or months with no participants to engage. The lower-than-expected recruitment to the trial meant that participant flow through the therapy process was not regular, and it was difficult for therapists to establish a routine of setting aside time for the research on a regular basis. Hence when the demand came, the ability to respond to it was hampered, affecting adherence to the trial intervention. Efforts to address these problems included the instigation of regular therapist group meetings in order to help raise the profile of the research and provide a forum for problem solving, and although these were productive initially, interest soon waned as the main problem of competing commitments and low participant recruitment persisted. Therapist drop-out was not a major problem despite the relatively long recruitment period of the trial (which was extended twice to more than 3 years), but over time the therapist roles evolved and changed and circumstances sometimes made it difficult for therapists to honour commitments made at the beginning of the research. These problems would have been averted if we had the resources to employ dedicated therapists to deliver the intervention.

9) *The confounding effect of testing*
In retrospect, it is believed that a major problem affecting engagement with the trial intervention was the confounding effect of testing for hepatitis C that was necessary in order to establish eligibility. This turned out to be both a positive and negative outcome of the research. Good ethical practice entailed pre and post-test counselling to help the service users understand the implications of testing. For many service users, this was the first time that hepatitis C became an issue for them, and an awareness of the current risk they were presenting became salient. Pre- and post-test counselling was guided by best practice in providing necessary and sufficient knowledge and understanding, at an appropriate level, ensuring that

sibility of other longer-term benefits. As such, it was relatively easy for service users to agree to take part in the research and receive their initial compensation for completing assessment measures, and then disengage from the research when further demands such as the trial intervention were arranged despite their informed consent to take part in the research. There might have been a tactical element to disengaging, whereby participants could "gamble" on the possibility of being randomised to the control intervention, which was a less demanding 15-minute non-interactive intervention, rather than the experimental intervention, which required up to four one-hour sessions of their time in personal therapy. In the intention-to-treat analysis, all participants were followed-up at six months regardless of whether they had engaged for any sessions of the intervention, and so they could also play a stalling game, holding off from the trial intervention until the time of the next research assessment, the easier part of the research and receive their second compensation voucher. In reality, the six-month follow-up was often stretched as late as possible if it was felt that there was still a chance that the participant might still engage in the intervention, but this did not improve adherence significantly. Additionally, it was felt that the introduction of compensation for the research-specific aspects of the trial might have worked against engagement in the trial therapy by encouraging participants to conceive of all aspects of the research as "paying for their time". This may have affected the experimental intervention much more than the control intervention. Compensation can increase recruitment under some circumstances, but it can also create other problems.

8) *Therapist issues*

Although modelled on research carried out in the USA, an important difference with this UK trial was that the therapists trained to deliver the interventions were not directly funded by the research. Rather, in keeping with the pragmatic implementation nature the study, all trial therapists were recruited from the services from which the participants were recruited and all were full-time NHS employees with caseloads and ongoing commitments. To enable them to take part, the therapists were relieved from some of their routine duties though without any other compensation. However, we found that the therapist motivation to take part to vary and some did not give the research

blood spot (DBS) sample [10]. Using the DBS, the testing was carried out in-situ by the service staff, and without the need for trained phlebotomists. Both the service staff and service users responded very positively to the introduction of this method of testing, and testing rates increased fivefold. However, even with this new method of testing, and even when the research team did testing opportunistically, a significant proportion of IDUs remained untested. Therefore, estimates of prevalence of hepatitis C within the population, although accurate, did not reflect the proportions of eligible participants that we anticipated due to the significant proportion of IDUs whose hepatitis C status could not be determined.

6) *Variation in service set-up*

Drug services were variably effective in participant recruitment. Some of this variation was accounted for by the differing levels of enthusiasm that the staff at recruitment sites had for the research. This seemed to be related to the service philosophy of care, treatment approaches (harm minimisation versus abstinence models) and the perceived value of the research. It is easier to encourage service users to take part in the research when service staff and managers are enthusiastic, when the research is perceived as an opportunity for innovation, and when the service has had previous positive experience of research. The other reason was related to the ease with which the research staff could recruit from each site, mainly as a result of service set-up. Research was made easier in those services which offered a strict appointment system, or where they had designated sessions for appointments at set times of the week, as opposed to more informal drop-in type systems.

Issues relating to the trial design

7) *Therapy compliance and compensation*

For taking part in the trial, monetary compensation in the form of vouchers was provided at baseline, post-intervention, and at six-month follow-up. Participants were not compensated for their attendance for therapy for ethical reasons, so that participants' motivation to engage in therapy was not influenced by financial reward. Although the availability of financial reward undoubtedly increased recruitment rates in this difficult-to-engage client group, it is believed that it may have played a role in the relatively poor adherence to the experimental trial intervention. Participants may have been motivated by short-term reward rather than the pos-

perceived risk of contracting it, in relation to other more immediate concerns. Although many service users were on a stable substitute drug treatment, continued drug use remained a significant problem for many, and an array of difficult legal, health, social, and psychological problems took precedence over the personal health risks of contracting a blood borne virus. Although these risks were serious and very real, in the context of other issues that service users faced, the need to address them immediately and participate in assessment and intervention was not a priority.

Issues relating to the service environment

4) *Definition of IDU*

During the design of the trial, estimates were obtained of the number of IDUs engaged and the proportion of new referrals to the service over the course of the research. However, the definition of IDU varies between "injected ever, even once"; or "only those currently injecting", or somewhere in-between. For this present study, the definition of IDU was operationalised to have "Injected at least once in the last twelve months". A subsequent revision to the research protocol changed this to "injected at least once in the last six months" in order to identify a more "at-risk" group, but this excluded a significant number of potential participants from our original estimates.

5) *HCV testing*

Apart from service users having injected within the last six months, the other main inclusion criteria for the research was that the participants be currently not infected with hepatitis C. This was established by a blood test within the last month, and prior to recruitment. It was assumed, and confirmed by the staff of the service, that testing for blood-borne viruses was a routine part of the service offered. However, in reality, the levels of testing were found to be far lower than expected, and this was initially a significant obstacle to recruitment. Whether testing was regularly and routinely offered or not, it was not regularly taken up, due largely to the need to attend a special clinic or visit the local hospital in order to have a blood sample taken. Somewhat unexpectedly, a proportion of IDUs claimed to be phobic about having blood samples taken, and a similar proportion were not keen to have someone else interfere with their veins. This problem was successfully addressed through the introduction by the research team of an innovative new method of testing for hepatitis C using a finger-prick dried

our attempts to overcome them, followed by a general reflection on the lessons that we learnt and recommendations for future research into this and related areas.

Issues relating to the client group behaviour and health

1) Chaotic nature

The chaotic behaviour of the IDU population has been well documented, and was anticipated to be a significant problem for our research. However, the scale of the problem was such that despite our best efforts to ensure that the measures and the interventions were as amenable to service users as possible, it still presented an obstacle over and above that anticipated. Disengagement with the treatment services, disengagement with the research, missed appointments, and concurrent forensic or health issues all impeded the progress of the research. In the context of larger and unexpected problems emerging in service users lives, their commitment to the research often was not sustained, even if their original intention to participate was genuinely made.

2)Service-user reporting of injecting behaviour

One of the main inclusion criteria for this trial was that the participants had injected at least once within the last six months. This was in order to identify a suitably "at-risk" group who could realistically benefit from the trial intervention. During the design of the trial, estimates were obtained of levels of injecting behaviour, but during recruitment we found significantly lower levels of recent injecting behaviour than anticipated, and this had an impact on the predictions of numbers of eligible participants over the course of the trial. The IDU's reporting of injecting behaviour may differ depending on how and by whom the question is asked, and that direct questioning by researchers may elicit lower levels of injecting than in reality. The two main reasons for this are the general social stigma, even amongst many drug users, of admitting to injecting behaviour, and possibility of sanctions within the context of drug treatment services that lead to lower self-reporting. Anonymous data collection of injecting behaviour, or indirect methods of estimating (such as key worker informants) may give more accurate levels of real injecting behaviour, but these are not likely to be achieved when service users are asked directly.

3) Importance and relevance of hepatitis C

Related to the issue of IDUs chaotic behaviour is the importance and relevance of being educated in hepatitis C, and the

and those not followed and between those who received EPC and SEC. On the primary outcome measure of the rate of seroconversion, 8 out of 62 patients followed-up at twelve months seroconverted, three in the EPC group and five in the SEC group, indicating incidence rates of 9.1 per 100 person years for the EPC group, 17.2 per 100 person years for the SEC group, and 12.9 per 100 person years for the cohort as a whole. Analysis of the secondary outcome measures on alcohol use, risk behaviour, psychological measures, quality of life, and service use measures showed no significant differences between the EPC and the SEC groups. However, there were significant changes on a number of measures from baseline values indicating positive change and improvement in these measures for both groups.

We were not able to prove the efficacy of EPC and hence its cost-effectiveness in comparison with SEC in the prevention of hepatitis C in IDUs. This was related to low recruitment and retention rates of the participants. Moreover there was a low adherence rate to EPC.

This paper provides an overview of the main problems that we faced and our attempts to overcome them, in the hope that it will guide other researchers in the field of addiction. Our findings and the lessons learnt may also be of general interest to researchers planning to conduct RCTs of psychological interventions in health care settings.

Main problem areas encountered

As with many large RCTs, a wide range of problems were encountered during the course of the research, some of which were amenable to minimisation by the research team, and some of which were beyond our control. The main problems affecting the outcome of the research were the lower than expected levels of recruitment to the trial, and the low adherence to the psychological intervention (only 45% of those randomised to the EPC intervention (4 interactive sessions) engaged for at least one session). Retention was a lesser problem, as more than 80% of those recruited were followed-up, and adherence to the informational one brief session intervention was not a problem, as more than 90% of those randomised to the SEC informational intervention received it. The reasons for these two main problems can be grouped under the following subheadings:

- Issues relating to the type of client group, behaviour, and health
- Issues relating to the service environment from which participants were recruited
- Issues relating to the trial design

There follows a brief discussion of these obstacles that we faced, and

Key words: Addiction; drug misuse; psychological interventions; randomised trials;

Introduction

Viral hepatitis C is a global public health problem, and has been considered one of the major challenges in the third millennium[1]. The hepatitis C virus (HCV) is a leading cause of chronic liver disease in the general population, with an overall prevalence in the USA of 1.8%[2] and of 0.5% in the UK[3]. Injecting drug use is the main route of transmission, mediated by the sharing of injection equipment, especially needles and syringes but also spoons, cotton filters and other paraphernalia[4].

The recently introduced Hepatitis C strategy for England[5] laid strong emphasis on preventing new cases of hepatitis C infection in IDUs by health promotion activities and the provision of needle exchanges schemes. This is best achieved in the context of treatment for drug dependence complemented with information about hepatitis C and harm minimisation messages. However, this new policy falls short of recommending specific preventive interventions which are evidence based; hence the importance of this project which aims to evaluate a new preventive intervention for Hepatitis C in IDUs.

We have reported the results of a randomised controlled trial of the effectiveness and cost effectiveness of enhanced counselling in the primary prevention of hepatitis C in injecting drug users[6]. The aim of the study was to develop and evaluate the effectiveness and cost effectiveness of enhanced prevention counselling (EPC) in comparison with simple educational counselling (SEC) in reducing hepatitis C viral (HCV) infection in sero-negative injecting drug users (IDU). Ninety-five IDUs were recruited and randomised to receive EPC (n = 43) or SEC (n = 52). Subjects were assessed at baseline using the Addiction Severity Index (ASI)[7], the Injecting Risk Questionnaire (IRQ)[8], and Drug Injecting Confidence Questionnaire (DICQ)[9]. The primary outcome was measured by the rate of sero-conversion at 6 months and 12 months from baseline and by the ASI, IRQ and DICQ at 6 months from baseline. Hepatitis C testing was undertaken by the innovative test of the dried blood spot (DBS) [10] tests, which increased, the rate of testing by 4 fold compared to routine blood testing. Seventy-eight subjects (82%) out of the 95 recruited were followed up at 6 months and 62 (65%) were followed up at 12 months. There were no differences in demographic, clinical and psychological characteristics between those followed up

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Conducting randomised controlled trials of psychological Interventions in the field of drug addiction – trials and tribulations

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إجراء الدراسات المقارنة الضابطة العشوائية للمداخلات النفسية في مجال الإدمان: محاولات و إخفاقات.

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Abstract

Background: We have completed a randomised controlled trial (RCT) of the effectiveness of enhanced prevention counselling (EPC) in the primary prevention of Hepatitis C viral (HCV) infection in injecting drug users (IDU). In the conduct of the trial we faced many challenges, which have not enabled us to recruit the required number of participants. Hence, we were not able to demonstrate the effectiveness of EPC in decreasing the incidence of HCV in IDUs.

Objective: To describe the challenges encountered in carrying out the RCT and critically discuss their implications for conducting RCTs of psychological interventions in the field of drug addiction.

Method: The challenges faced were organised into 3 main themes: issues relating to the type of the client group, behaviour and health; issues relating to the service environment from which participants were recruited; and issues relating to the trial design

Results: The main challenges encountered were related to the chaotic behaviour and motivation of drug users, to the high disengagement rates with the treatment; to issues relating to the service environment such as the definition of IDU, HCV methods of testing and to the variation in service set-up; to issues relating to research design including compensation for participation and the use of trained regular staff rather than dedicated research workers as therapists.

Conclusion: The main lessons learnt were that piloting of a new intervention is a crucial first step before conducting pragmatic RCTs of psychological interventions in the field of addiction; that an infrastructure and culture for psychosocial interventions is needed to enable applied research in the service environment, and research funding is needed for enabling the recruitment of dedicated trained therapists for the delivery of these interventions.