The Job Retention and Rehabilitation Pilot: reflections on running a randomised controlled trial

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A report of research carried out by the National Centre for Social Research on behalf of the Department for Work and Pensions
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<tr>
<th>Abbreviation</th>
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<tr>
<td>CATI</td>
<td>Computer Assisted Telephone Interview</td>
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<tr>
<td>CBT</td>
<td>Cognitive Behaviour Therapy</td>
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<td>COI</td>
<td>Central Office of Information</td>
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<td>DH</td>
<td>Department of Health</td>
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<td>Disability and Work Division</td>
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<td>DWP</td>
<td>Department for Work and Pensions</td>
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<td>ERAS</td>
<td>Employment Retention and Advancement Scheme</td>
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<td>General Practitioner</td>
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<td>National Centre for Social Research</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>OCS</td>
<td>Outcome Survey</td>
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<td>SOHAS</td>
<td>Sheffield Occupational Health Advisory Service</td>
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<td>SoSOSOC</td>
<td>Survey of Screened-Outs and Controls</td>
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<td>Abbreviation</td>
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<tr>
<td>SPRU</td>
<td>Social Policy Research Unit</td>
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<td>SSP</td>
<td>Statutory Sick Pay</td>
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Summary

This is an account of the operation of the Job Retention and Rehabilitation Pilot (JRRP), the first randomised controlled trial within a large-scale voluntary labour market programme in the United Kingdom (UK). JRRP is being evaluated by the National Centre for Social Research (NatCen), in collaboration with the Social Policy Research Unit (SPRU) at the University of York, and the Urban Institute (Washington DC).

JRRP was developed to test interventions that might decrease sickness absence and increase job retention for people off work sick for between six and 26 weeks. The trial was run in six areas and potential volunteers were screened by a central Contact Centre from April 2003 to December 2004. Those eligible and ‘likely’ to lose their job were randomised to one of four equally sized groups: a workplace, health or combined intervention or a Control Group. The workplace intervention had to focus on bringing about change within the workplace and could give advice only about the workplace or how people work. The health intervention had to be delivered away from the workplace, treat the mind or body of the participant and advise only about health. The combined intervention could be any of these. In total, 2,845 people were screened and randomised.

This report is based on data collected by three ‘research advisers’ who conducted site visits to providers and the Contact Centre to monitor the trial throughout its operation, as well as data from two surveys of participants and the screening instrument. A final report will follow on the JRRP services and their impact, costs and benefits.

Feasibility, implementation and set-up

A randomised controlled trial to consider how best to assist people on sickness benefit to stay in or return to work was first proposed in 1999. During the early development, much of the basic design was decided, including the four-way randomisation and restricting it to those off work for at least six weeks. Nine potential providers set out how they might market the trial and provide interventions. An evaluation feasibility study was conducted and a screening instrument developed to identify those at risk of losing their job.
As the providers had different views about marketing and the interventions, variations in these were tolerated as long as they all marketed to the same client group, and what was a workplace intervention for one provider would not be health for another, and vice versa. Only five areas were to be standardised across providers: screening, consent, randomisation, the Control Group and data recording. Providers generally agreed that they did not want contact with controls, to avoid ethical issues about refusing help.

The main elements of the design by the end of the feasibility stage were that providers would carry out local marketing, and volunteers would make contact by telephone. For standardisation and to avoid contact between providers and controls, the Contact Centre would be a separate entity. The contact would cover eligibility, screening for risk, consent to randomisation, and (as recommended at this stage), randomisation. Those randomised to an intervention would be notified daily to providers, who would collect consent for treatment. The nine providers supplied detailed proposals, and four were selected.

The implementation stage followed, during which the Department for Work and Pensions (DWP), Department of Health (DH) and National Centre for Social Research (NatCen) worked with the providers to put the trial infrastructure in place. Naturally, this produced some change in the design. Randomisation was separated from screening to rule out any possibility that the screening interviewer could influence the allocation. To help standardise the consent process for intervention groups, a short video was produced explaining the randomisation, what would happen next, and emphasising that the trial was voluntary.

But, in broad terms, the design agreed at the feasibility stage was implemented. During implementation, the providers and Contact Centre set up their operations. The screening questionnaire was developed, and the randomisation programme and procedures written and tested. The video was produced and consent forms and patient information sheets were designed. The ‘boundaries’ for the three intervention types were agreed upon, the Management Information System (MIS) was designed and protocols for information transfer agreed on. The trial protocol was (successfully) submitted to the West Midlands Multi-Research Ethics Committee (MREC) for ethical approval, and provider and Contact Centre staff were trained. However, the implementation stage did not test the procedures on real cases, so unsurprisingly, some of the systems were found to be less than watertight and changes had to be made during the trial.

Recruitment and marketing

As the eligible population was not identifiable using official statistics, each provider developed a recruitment prediction based on their expectations, seasonal variations and information about national sickness absence. Recruitment began on 31 March 2003 and continued for 20-21 months. Two providers recruited around half of the number predicted, and the other two between a quarter and a third.
Eligibility was determined for 94 per cent of callers. A third were ineligible, almost half because they had been off sick longer than 26 weeks. Two in five were not working, a third had not been off sick long enough and a quarter were not in the pilot areas. Only six per cent of eligible callers were not invited to join the trial because they were not at risk of losing their job (‘screened-out’). Almost all eligible and screened-in callers agreed to join (99 per cent).

Fifty-seven per cent of trial entrants were female, and they were concentrated between the ages of 30-59, older on average than the UK population in work. Three-quarters had been working at least 35 hours per week, most (94 per cent) were permanent employees and three per cent were self-employed. This was lower than among UK workers (13 per cent), possibly indicating a failure to reach and/or attract this group.

Around half worked in the public sector, considerably more than the UK population (28 per cent). Two-thirds thought their manager was understanding about their sick leave, and 84 per cent liked their job. Just over half had been off sick for six to 12 weeks and 15 per cent for 20 weeks or more, most commonly with musculo-skeletal (44 per cent), mental health (35 per cent), or cardiovascular (13 per cent) conditions.

Providers marketed the trial to general practitioners (GPs), employers, and potential volunteers. They could not recruit clients directly (to avoid Control Group contamination), and to avoid coercion, GPs and employers were not allowed to refer people directly. The marketing materials restricted the amount of information about treatments and had to mention certain straplines (e.g. benefits would not be affected; treatment could not be guaranteed). Many of these restrictions were a condition of receiving ethical approval.

Providers found GPs difficult to engage. All felt that branded Med3 forms (with detachable slips sent to the Contact Centre) were a useful tool, as they helped persuade GPs that the pilot was authentic and ethical, and prevented them from ‘cherry-picking’. However, there were difficulties and delays in producing these.

Similar challenges were encountered with employers as it was not always obvious whom to approach, and was not easy to get them to see the benefits. With hindsight, some providers felt that they should have started marketing to employers earlier. Several staff commented that employers might not provide a representative sample, as certain types were more accessible than others. GPs might be better as their patients are drawn from the full range of employers. Another disadvantage of using employers is possible coercion, but this was rare.

Providers used a range of methods to reach volunteers, including leaflets, freepost slips (to be sent to the Contact Centre), posters, local press and radio, GPs and employers. The way that clients heard about the trial reflects the marketing, with GPs being the principal source. Employers and leaflets also played an important part, and a small proportion heard through a friend or relative, other organisations, or radio and newspaper advertisements.
Restrictions on the marketing were perceived as barriers, as staff felt that the messages they had to put out were not immediately appealing. Focusing on the fact that people had to be at risk of losing their job was felt to be unhelpful as staff felt that clients did not accurately assess their own risk. The prescriptive nature of the marketing content also introduced delays and bureaucracy.

Once it became clear that recruitment was a problem, DWP/DH led a number of initiatives, including a trial of direct marketing at GP surgeries. There was no evidence of any large effect and feedback from recruiters suggested low interest. Providers felt its usefulness was constrained by the fact that direct appointments could not be made questioned whether GP surgeries were the best setting, preferring shopping centres.

With hindsight, marketing staff perceived the need for more initial research on clients, and a longer build-up period. Although initially providers were keen to conduct local marketing, by the end, they would have welcomed greater DWP/DH involvement. Higher profile marketing (press/radio/TV) was also suggested and using the same brand name in all areas. One provider commented that recruitment could have been increased had they (or the Contact Centre) been able to contact potential recruits directly or GPs allowed to directly refer. Communication was another area singled out for improvement and a final suggestion was to increase the length of the trial once it was realised that recruitment was low.

Reflections on recruitment and marketing

- More research into the population may have produced more accurate predictions.
- The marketing and the voluntary nature of the trial both influenced the composition of the sample, as marketing was often focused where the highest returns were expected and those with low motivation will not have volunteered.
- Brand name credibility and the legitimacy of the pilot were seen as important.
- The marketing is likely to have been more effective if it had begun before the trial started.
- Recruitment may have been higher if central initiatives such as employer mail outs, field advisers and branded Med3 forms had begun earlier.
- A national brand name would have simplified central marketing.
- The restrictions on content were believed to have reduced the success of the marketing.
- The restriction of direct contact between providers and volunteers should be reconsidered for future trials faced with similar recruitment issues. A higher risk of contamination might be acceptable if the method delivered significantly more volunteers.
• For this population and trial design, the most effective and ethical recruitment appears to have been through GPs rather than employers.

• When a trial is totally reliant on marketing to draw in volunteers, the resources used for this should reflect its importance.

• It may have improved recruitment for other more specialised organisations to have conducted marketing, although they may not be as motivated as a provider.

Screening tool and contact centre

As well as checking eligibility and assessing volunteers’ risk of losing their job, the Contact Centre advisers also read out a standard script to ensure that ethical obligations were met. Providers were concerned that the Contact Centre might have been a barrier to entry, because it used the phone and because of the screening itself. However only two per cent refused the screening, which suggests very little deterrence.

The risk assessment aimed to reduce the proportion of trial entrants who would have returned to work whether or not they received help. JRRP sought to intervene early even though a high proportion return to work anyway in the first weeks – either the trial needed more volunteers to compensate for this ‘deadweight’, or they had to be identified and ‘screened-out’. A screening tool was developed specifically for JRRP as no existing tool was applicable. The review and testing process identified the five strongest predictors of return to work, which were entered into a model to produce a risk score algorithm.

Once the trial had been running for some months, research by the Research Advisers revealed that although the Contact Centre advisers gave a good first impression, the screening process was failing to communicate some key messages. Improvements were tested and the script revised in June 2004. The questions largely remained the same, but some were re-ordered to improve the flow, and on screen guidance added. The research also identified a need for refresher training of the Contact Centre advisers to ensure that they read the questions exactly as dictated, did not add explanations to the script and provided accurate information. There was little evidence that any aspects of the screening were off-putting. Those found to be ineligible or screened-out did not generally exhibit adverse reactions. There was some evidence of contaminatory information being given, but not extensively. At the start of the trial, the IT had not been implemented fully, leading to a failure to identify repeat callers, and to permanently store some of the data captured. In June 2004 a new web-based system corrected these problems and implemented the new script.

Almost all survey respondents remembered phoning the Contact Centre, and most had a good understanding of the trial, including a good awareness of the Control Group. However, a minority (18 per cent of controls and 32 per cent of screened-outs) would have liked more information. Most controls (86 per cent) understood they had a choice as to whether to continue taking part.
Effectiveness of the screening tool

The Control Group was used as a representative sample of trial entrants to measure the trial’s deadweight rate (the proportion who would have returned to work whether or not they received help). A telephone survey of controls and screened-out volunteers provided an early estimate of deadweight, measured as the proportion of the Control Group that had returned to work for 16 hours or more 28 weeks after first going off sick (41 per cent). A more conservative estimate including work of less than 16 hours increases the rate to only 45 per cent, thus the target of deadweight below 50 per cent appeared to be met. The rate of return to work (16+ hours) was significantly higher among screened-outs (70 per cent), which also provides evidence of success.

Reflections on the Contact Centre and screening

- Overall the Contact Centre and screening worked well, with the advisers building rapport and providing a good service.
- Using the telephone did not seem to generate difficulties although we do not know whether a significant group did not volunteer because this was a barrier.
- The advantages of centralising the process appeared to outweigh the disadvantages.
- Only a small percentage were screened-out, which implies that the trial might have been able to rely on self-screening.
- The tool met its target of reducing deadweight to no more than 50 per cent.
- The Contact Centre advisers did not know which questions contributed to the risk assessment but it was easy for them to identify themes linked with being screened-out.
- The assessment was also blind to providers, which created some difficulties as they received no screening information and so had to ask clients the same questions again.
- Before implementation the questions and script needed more thorough testing, as did the IT system to ensure that all aspects had been implemented.
- More training of the Contact Centre advisers by the Research Advisers before go-live would have improved the standardisation of the screening interview.
- Visits to providers by Contact Centre advisers may have increased their commitment to the pilot, but introduced an opportunity to share inappropriate information, and increased the chances of contamination and incorrect information being given.
- The transparency and simplicity of the eligibility criteria allowed ‘self-screening’ which probably reduced the volume of ineligible callers. The risk assessment was more difficult to explain to volunteers.
Many providers suggested that recruiting before six weeks of sick leave and/or waiving the requirement for continuous absence would have made it easier to help clients. The screening tool would have addressed the disadvantage of higher deadweight.

It was also suggested that volunteers within two years of planned retirement be ineligible, as there can be a considerable incentive to take medical retirement.

The geographical criteria was seen as restrictive by some, although larger areas served by a single central office may not have been in the interests of clients.

Having to be at risk of losing your job was perceived as a disincentive to volunteering as people who could have benefited may have been deterred because they perceived themselves as not at risk. The Contact Centre often found this uncomfortable to explain.

Motivation to return to work was not part of the eligibility criteria, but it became apparent that some did not want to return.

Randomisation

NatCen, independent of the Contact Centre and Service Providers, conducted the randomisation. Twice daily the Contact Centre sent a secure email containing the basic details of callers who had consented to randomisation. A bespoke program conducted checks, allocated callers to one of the groups, produced a letter to notify them, and a file for each provider containing those allocated to Intervention Groups. The Intervention Group letter did not specify the exact allocation because it was expected that clients would be less likely to anticipate benefits from Workplace relative to Health interventions. Delaying the notification to a point where the provider could provide more details was designed to prevent withdrawal through ignorance. The letters included a freephone help line number.

Block randomisation was used to prevent each area receiving a large number in any one group over a short period, and to make it difficult to predict the next allocation. This, coupled with the fact that allocations were not communicated to the Contact Centre, greatly reduced the potential for anyone to influence the allocation in any way. Administrative data was monitored weekly to check that equal numbers were allocated to each group within each area. By the end of recruitment, almost exactly equal numbers had been allocated to each group and there were no substantial differences in the characteristics of the groups. Six random allocations occurred erroneously.

The majority (97 per cent) were processed from consent at screening to randomisation within two working days. The delays for the remaining three per cent were mostly short and had no significant impact. Eighteen per cent withdrew after being allocated to an intervention but consenting to receive it. This was highest among the workplace and lowest for the health group and varied by area from four to 29 per cent. Not all withdrawals were chosen by the client. Survey data suggests that about a fifth who left early did so because the provider had either not contacted or offered them any treatment.
The help line was intended to give the Control Group access to some support that would not contaminate them and the team taking the calls were trained not to suggest actions they would not have thought of otherwise. However, more calls were received from Intervention Groups than from controls (86 and 33 respectively). The former tended to call for reasons related to contacting the provider, whereas controls called because they were upset or disappointed with their allocation. The volume of calls was lower than anticipated, which could indicate that only a few participants experienced difficulties. However, some calls that might have been directed to the help line were actually made to the Contact Centre. The reactions of the Control Group are important because disappointment might affect their subsequent behaviour. Despite the small proportion that used the help line, the survey shows that most were quite disappointed.

Less than one per cent of callers refused to be screened because they did not agree with random allocation, and only one per cent refused consent to be randomised. This suggests that people did not react negatively to randomisation once they had volunteered. However, we do not know whether randomisation put off those who did not volunteer in the first place.

Reflections on randomisation

- Most provider staff and volunteers accepted the randomised controlled trial methodology.
- The transfer of client details from the Contact Centre, through randomisation to providers, was timely and generally worked well.
- The randomisation algorithm allocated entrants to the four groups as expected. Inappropriate randomisations were rare, but more robust checking procedures should have been implemented at an early stage to prevent delays and errors.
- The notification letter was a useful confirmation and permanent record for trial entrants. Unfortunately controls were sometimes confused rather than reassured, perhaps because sensitive wording was prioritised over clarity.
- The help line was more useful for participants who had lost contact details, than as support for randomisation. Some controls used it, which indicates that it was probably necessary, but although most did not call, disappointment was common.
- The level of attrition differed by randomisation group and area, but was no greater than expected and was not seen as a significant problem by providers.

Service delivery

The procedures for making initial contact were designed to ensure that clients were phoned as soon as possible and invited for a meeting, which most had within two weeks of screening. However, 15 per cent waited three to four weeks, and three per cent five weeks or longer. For the most part providers implemented the contact
procedures as intended. In a couple of areas with markedly higher attrition, they were not being implemented as prescribed, primarily because of specific staffing arrangements.

Clients were shown the video, told their group allocation, given an explanation of their intervention and asked to give written consent. Provider and clients both thought the video was clear, logical and comprehensible. Clients were not supposed to be told their intervention group until they had heard about the randomisation through the video. Whilst this was generally followed, some were told during the initial telephone call, either because case managers were not aware of the correct procedure or clients insisted on knowing.

An assessment was often conducted at the initial meeting and an Action Plan drawn up. Providers differed in the extent to which they saw the plan as a formal or a working document. Some were using it primarily for contractual purposes without recording any detail or revisions, whereas others were continually updating it alongside their own case notes.

During their early visits, Research Advisers observed patchy awareness of the trial and evaluation objectives and procedures, and a perception that service delivery was of greater importance than the research. So, in order to raise the profile of the procedures, training workshops were held for all provider staff and a handbook issued. These improved adherence to the consent and Action Plan procedures, although a subsequent examination of a random sample of cases revealed some areas where guidance was still required.

A clear demarcation was intended between the services in the health and workplace groups, and guidelines prescribed which treatments were appropriate to avoid ‘contamination’. The combined group could not be contaminated by definition. Providers were for the most part clear about what was, and was not appropriate to offer and had come to terms with the clearly defined menu of treatments.

An assessment of contamination was made using information about actions and treatments for every health and workplace client (up to October 2004) in the MIS database. This identified a small number of clients receiving inappropriate treatments, particularly in the earliest months. Preliminary survey data confirms that such contamination was reasonably low, affecting ten per cent of workplace and seven per cent of health clients (according to a self-report measure). There was some evidence that contamination was more likely where the case manager worked with clients from more than one group or where their background covered both.

A more contentious issue was that of complying with guidelines that advice given in the health or workplace interventions should not ‘trespass’ on the other’s territory. It was apparent early on that this were not being adhered to. The reasons included patchy awareness of the guidelines; insufficient training of new staff; difficulty in interpreting the guidelines; ethical dilemmas when faced with withholding advice; conflict with existing professional codes; and the employment background of case
managers. DWP decided that a clear demarcation was essential, and the workshops were used to provide further training. These also sought to communicate that clients were still in the trial after being discharged and thus any advice given at exit had to be appropriate to the intervention. Although the workshops helped to clarify advice-giving, the tension between the constraints of the trial and the practitioner’s professional code of ethics continued.

Providers were required to design and set up their own database, but all experienced problems with this, and felt that, with hindsight, a standard database that was designed, controlled and pre-tested centrally would have been preferable. Providers had ongoing difficulties in understanding the data entry requirements, and had to conduct a large amount of retrospective data entry at the end. The development process did not generate sufficient changes at the early stages, partly because providers did not have their ‘users’ in place yet. The difficulties with the database are likely to have reduced the quality of the data recorded.

The funding model for the pilot was felt to have influenced service provision. Fees were paid per client giving written consent, which discouraged drop out immediately after randomisation. However, it could be detrimental if achieved at the expense of not allowing the client sufficient time to consider whether to participate. An extra fee was payable if a client returned to work. Whilst this acted as an incentive, it may not have promoted the client’s best interests if a client did not prioritise returning to work themselves. Health treatments were seen to be relatively costly which constrained what could be offered.

Reflections on service delivery

• JRRP demonstrates the benefits of putting in place procedures for delivering specific aspects of the service in advance.

• Another lesson is the desirability of maintaining a measure of standardisation and central control – where the consent procedures were adapted locally to suit different models, difficulties occurred.

• Providers would have found it easier if the information requirements had been more ‘user friendly’ and there had been a centrally designed database.

• The separation of providers from any contact with controls will pay dividends in enabling a ‘clean’ and meaningful comparison between the treatment and Control Groups.

• The complexity of three treatment groups increased the risk of contamination and ensured that it was an ongoing issue. Had there been just two groups (treatment and control), it would not have surfaced as an issue. It would also have been less marked had it been confined to treatments, as it was not essentially a difficult task for providers to work with clearly delineated treatments.
• Inappropriate advice-giving was unlikely to be recorded and is therefore much more difficult for the evaluation to detect. This diminishes the ability to measure the differential effectiveness of a health versus a workplace focus. Nevertheless, the separation of the treatment options means that it will still be possible to measure the relative effectiveness of a predominantly workplace-focused and health-focused approach.

• The cost of attempting to achieve a clear demarcation in terms of advice-giving was considerable, as it provoked antagonism amongst providers who felt it was unrealistic and unworkable. Any future versions of this randomised controlled trial format would be advised to consider making the issue of advice one that cuts across all interventions.

• The difficulties around advice-giving would have been easier to anticipate if the first months of live running had been accepted from the start as part of the development stage.

• The fundamental importance of ensuring all players are thoroughly briefed at the start is another key lesson. Any training should include the rationale for guidelines.

Winding down the trial

Recruitment ended in December 2005 but treatment continued until 31 March 2005. Some providers had been concerned about providing a satisfactory service to vulnerable clients entering at the end of recruitment, but in the event, experienced fewer problems than anticipated. They continued with the consent procedures in the same way as before with the exception of alerting clients to the pilot’s end date, which did not have a perceptible impact on participation. The wind down had little effect on Action Plans except that clients were told that any new actions would have to be completed before the end date.

A number of measures were put in place to ensure that treatment could be completed within the time remaining, including speeding up or intensifying treatments, finding alternative treatments, and referring clients to other agencies and subcontractors. It is likely that clients benefited from the higher level of input that case managers were able to provide towards the end. Providers generally felt that the measures taken to deliver treatments during wind down worked well.

An area of concern was the fact that staff were unable to provide continued treatment and support to those returning to work towards the closing date, which would diminish the boost offered and reduce the number of successful outcomes. In some cases, providers managed to refer clients to alternative agencies for this type of support.

For providers delivering the pilot alongside other core activities, it was easy to regulate staffing levels and there were unlikely to be staff leaving as a result of the
pilot ending. However, for those set up specifically to deliver JRRP, staff were naturally looking for other jobs. Generally, these providers felt that they had managed to regulate staffing levels satisfactorily by redeploying and extending the contracts of existing staff.

Dealing with the database and administrative records at the end proved to be quite challenging, as providers were unclear about exactly what was required. The requirement to wipe the data caused concern where a provider was using the database from its core business and some had concerns about client confidentiality.

Reflections on wind down

- A key lesson is the importance of forward planning – providers who had developed a specific wind down strategy felt that it had paid dividends.
- The DWP guidance on the wind down process was helpful and it would be useful to have something similar to work to in any future trial.
- For providers, the need to maintain recruitment as long as possible had to be balanced against the need to provide as full a service as possible to late entrants.
- It was viable to stick to the same consent/assessment procedures during wind down.
- Having to work to a tighter time frame during wind-down can encourage creative thinking about types of treatments and the timeframe in which they are delivered.
- When staff have to adapt from a client-centred to an administrative role or have to work with clients from different groups, there are implications for stress levels and morale.
- Forward planning is important with regard to systems and record keeping. It would have been beneficial if providers had fully developed and tested the IT systems before live running.
- An area of considerable difficulty for providers was obtaining outcome data from clients.

Management, communication and evaluation

The project management team was split into two discrete parts: Disability and Work Division (DWD), in London, had responsibility for the evaluation, and the contract management group within Jobcentre Plus in Sheffield, had responsibility for service delivery. Providers would have preferred a team at one location and a management structure with a clearly identified project manager to provide a clear management style and focus. Frequent changes of personnel meant that providers tended to be confused about who was managing the project.
The management team set up two initiatives to act as communication channels, a series of provider workshops to exchange ideas between providers and management, and the NatCen Research Advice team to monitor trial procedures and act as an intermediary. Providers considered both helpful, but felt that a more strategic approach was needed towards managing communication on a day-to-day basis.

It was felt that communication between management and providers could have been improved with more clearly defined channels of communication, and by keeping lines of communication as short as possible. The contract management group met providers on a regular basis to discuss contractual issues, but providers felt that more face-to-face contact would have fostered a more ‘collaborative’ style. It was easier to resolve issues face to face rather than via email. Issues around communication were not confined to providers and the management and evaluation teams, but also occurred within and between providers and their subcontractors.

Providers identified some areas where they would have valued more information, including the Contact Centre, their performance in relation to other providers, and the evaluation. Being better informed about the evaluation would helped them understand the interviews clients were doing, what it could achieve and countered any scepticism about its value.

Reflections on management, communication and evaluation

- A key theme emerging is the importance of establishing and maintaining good working relationships. These are fostered by a clear, accountable management structure combined with effective communication.

- Whilst government departments have their own established ways of working, it is imperative to find ways of adapting them. The running of the pilot would have been more effective if a dedicated project team had been set up in one geographical location.

- Despite it being policy within government departments to move staff on at regular periods, there would have been advantages to ensuring maximum continuity.

- A clearly defined management hierarchy would have helped all players understand who was running the trial, had responsibility for taking decisions and was accountable.

- A clearly defined person heading up the management team would have been able to provide a clear steer, co-ordinate the team, arbitrate disagreements, and speed up decisions.

- The trial highlights the importance of ‘active management’ of communication, along with maintaining short and clearly defined communication channels.

- A key strength was the pilot’s ability to take retrospective action where necessary, such as with the marketing, the Contact Centre script, and the provider training workshops.
• The provider workshops were a potentially valuable forum, but the ongoing problems of communication tended to prevent them reaching their full potential.

• The Research Advice role turned out to be flexible as envisaged, and invaluable for monitoring progress, checking the data collected, monitoring the Contact Centre and providers and identifying where remedial action could improve the quality of the trial.

• The Research Advice role turned out to be less effective in providing speedy and consistent responses to provider queries. With hindsight, acting as broker between providers and management may have lengthened lines of communication and contributed to a more distant relationship between them.

Conclusions and recommendations

Despite problems with recruitment most of the key aspects of the trial’s design worked as intended. Screening and randomisation ran smoothly and fulfilled their aims. Consent procedures were adhered to and overall attrition levels were no higher than expected. Interventions were delivered without very high levels of contamination in terms of actual treatments, although advice-giving was a problematic area. Management and communication were also problematic and problems were also experienced with the management information system.

Recommendations regarding marketing and recruitment

• More resources need to be invested in obtaining information about the target population.

• Consideration should be given to starting marketing earlier, during implementation.

• The possible trade-off between preventing contamination of the Control Group and effective recruitment should be considered.

• Where ethical considerations allow, there should be careful scrutiny of marketing messages, and consultation with providers about them.

• Future trials need to consider the effect of sources of recruitment on the representativeness of the sample.

Recommendations regarding screening and randomisation

• Testing and monitoring of such a key element of the trial should be included.

• Future randomised controlled trials should also take a centralised approach to screening and randomisation.

• The screening tool should be fully tested before go-live, including a pilot with volunteers.

• Contact Centre advisers should receive detailed training before go-live.
Recommendations regarding service provision

- The consent procedures could be repeated with few modifications, but should always be administered face-to-face.
- More thought is needed as to the purpose of Action Plans, especially whether it is necessary to gain a signature for every revision.
- A future trial should attempt to anticipate difficulties with service provision via discussion with staff before go-live.
- A bedding-in/piloting period should be considered as part of the development.
- Training (and other forums) should always provide the rationale for procedures.
- Early training should give detailed information on the evaluation, to aid understanding and to focus attention on the trial as a research study.
- Future trials should consider advice-giving before go-live and in consultation with providers. It might be more workable to allow advice-giving to be cross-cutting.
- Thought should be given as to whether a four-way trial is necessary, or whether two-way would give the same results, with lower risk of contamination.
- Future trials should design wind-down procedures in detail at set-up.

Recommendations regarding management and communication

- Consider how an accessible management structure can be tailored to best fit the particular trial, rather than attempting to fit the trial into a pre-existing structure.
- Turnover in the management team should be kept to a minimum if possible.
- A ‘partnership’ approach to communication should be considered, seeking consultation from an early stage with all those involved.
- Clearly defined two-way channels of communication need to be set up at the start. Dissemination of information should be proactive and timely.
- Members of the management team should consider making regular personal visits to providers to facilitate communication and working relationships.
- Provider staff are likely to benefit from receiving early information on the evaluation, especially where this involves asking them for information.

Recommendations regarding data collection and evaluation

- The evaluation and management information database should be developed and controlled centrally.
All interested parties should be consulted during development and given sufficient training in its use before ‘go live’.

Data collection needs to achieve the right balance between the natural desire for detailed information, and the practical limitations of what providers are willing to do.

Substantial changes during live running can increase workloads and affect morale and should be avoided.

Future trials should consider if data recording can be incentivised to improve quality.

Consideration should be given about how best to reduce the level of survey non-response among controls, perhaps by using incentives.

The Research Advice role performs the necessary function of ensuring trial procedures are followed and in evaluating the overall running of the trial. However, this role needs further consideration, in terms of its position in the management hierarchy and communication structure, decision-making powers, and location.

If not based at providers, Research Advisers need to promote active and regular communication with providers.

JRRP has shown that screening and random assignment can be conducted effectively and ethically in this context. The experience of running this trial provides many lessons that future randomised controlled trials can draw on in reaching the most effective design in this and other policy areas.
1 Introduction

This is an account of the operation of a randomised controlled trial, the Job Retention and Rehabilitation Pilot (JRRP). This trial represented the first use of random assignment within a large-scale voluntary labour market programme in the United Kingdom (UK). It is anticipated, therefore, that there will be significant interest not only in the substantive findings but also in the trial procedures. The purpose of this report is to provide an accessible description of these procedures, accompanied by an assessment of their strengths and weaknesses.

This introductory chapter explains briefly the objectives of JRRP (Section 1.1) and the main features of the trial design (Section 1.2). The methods used to evaluate the trial are described in Section 1.3. An outline of this report follows in Section 1.4.

JRRP is being evaluated by the National Centre for Social Research (NatCen), in collaboration with the Social Policy Research Unit (SPRU) at the University of York, and the Urban Institute (Washington DC).

1.1 Objectives of the Job Retention and Rehabilitation Pilot

The Job Retention and Rehabilitation research trial was developed to test interventions which might decrease the length of sickness absence and increase job retention for people with a health condition or impairment. In the UK since the early 1980s, the number of people receiving incapacity benefits has been increasing and this cannot be explained by any worsening of the health of the population. There is also concern over the incidence of sickness absence, particularly regarding those on longer term absence, who are more likely to be at risk of losing their job or their business because of their illness, injury or impairment and many of whom do not work again.
For some people, long-term sickness absence leads to a claim for incapacity benefits. Currently 7.6 per cent of the working age population are on incapacity benefits because of a health condition or impairment. When people start to receive these benefits, around 90 per cent say that they expect to return to work but in fact more than 40 per cent will still be in receipt of these benefits a year later¹. Just over 50 per cent of current recipients of incapacity benefits have a claim that has lasted five years or more.

Although not all those on certificated sickness absence or incapacity benefits would define themselves as disabled, evidence shows that employment rates fall with the onset of a disability and continue to fall the longer the disability spell lasts (Jenkins and Rigg, 2004). Labour Force Survey data show that in spring 2003, approximately 6.9 million people of working age reported being long-term disabled and approximately 5.4 million declared a work limiting disability (Tibble, 2004). The unemployment rate for disabled people in spring 2004 was about seven per cent compared to an unemployment rate amongst non-disabled people of around four per cent². Disabled people are very much more likely to be economically inactive (around 46 per cent compared to approximately 16 per cent of non-disabled people³).

Such statistics reinforce concern with difficulties in both maintaining employment and improving labour market outcomes for people with health conditions and for disabled people. The Government’s concern to prevent long term incapacity, improve return to work rates for people on sickness absence, and increase their employment retention was the basis for JRRP.

The purpose of the JRRP trial is to evaluate the impact of intervening early among the target population of people who have been off work due to sickness or disability for between six and 26 weeks and who are at risk of losing their job or business as a result. The pilot aims to demonstrate whether one of three types of boost to existing services affects the rate of return to work and job retention. The outcome of the pilot will guide future policy priorities.

² The unemployed are still considered to be economically active. DWP in-house analysis Labour Force Survey, spring 2004.
1.2 Design of the trial

Along with one other recent trial\(^4\), JRRP is unique amongst UK welfare to work initiatives, as it was designed from the start to be run as a research project, with evaluation fully integrated into the design. To ensure the evaluation is as robust as is possible, the pilot used random assignment. This is the first time this had been attempted on a large-scale voluntary labour market programme in the UK\(^5\). The design is also unique in that three models of intervention are being tested.

The basic features of the trial are as follows:

- The trial was run in six areas of the UK;
- It was aimed at those in employment of 16 hours or more a week who had been off work because of sickness or disability for between six and 26 weeks;
- Those interested in taking part volunteered by calling a central Contact Centre;
- Those eligible were screened, and only those ‘likely’ to lose their job were accepted onto the trial;
- Those eligible and screened-in were randomised to one of four equally sized groups: a workplace, health or combined intervention, or a Control Group;
- The impact of the interventions will be measured by comparing subsequent return-to-work rates for the four groups.

1.2.1 The areas

JRRP was run in Greater Glasgow, Newcastle and North Tyneside, Teesside, Sheffield, Birmingham and West Kent and these six areas were covered by four Service Providers. The actual areas covered were much larger than the names suggest. For example, the Glasgow area covered not only the city of Glasgow, but extended into surrounding counties, such as Lanarkshire, Dumbartonshire and Renfrewshire. A single provider covered each area, although two Service Providers each covered two areas. In every area all three interventions were offered. In two areas, one of the interventions was provided by the Service Provider, with the other two interventions each being provided by a separate organisation through a subcontracting arrangement.

\(^4\) The Employment Retention and Advancement Scheme (ERAS), another randomised controlled trial which is piloting services for lone parents and the long-term unemployed.

\(^5\) ERAS was launched shortly after JRRP.
1.2.2 Eligibility
To be eligible for JRRP several conditions needed to be satisfied. A client must:

- have been employed or self-employed and working for 16 hours a week or more;
- have been off work sick for between six and 26 weeks;
- have been living and working within one of the pilot areas;
- not be within 18 weeks of planned retirement.

Reflections on these eligibility criteria can be found in Section 4.6.2. To be entered onto the trial, clients had to be both eligible and to be ‘screened-in’. The ‘screening in’ process was designed to identify those with (on average) a greater than 50 per cent chance of losing their job if they received no intervention. The screening tool was delivered at a national Contact Centre based in Glasgow.

1.2.3 Marketing
There are no centrally held lists of those absent from work because of sickness or injury, so the eligible population could not be identified easily. Instead, Service Providers implemented a variety of methods of marketing the pilot, including recruitment via general practitioners (GPs) and employers, and general advertising (posters, radio, etc.). Potential participants needed to self-refer by calling a Contact Centre, or sending a freepost slip (where a volunteer could send their details to the Contact Centre asking to be called rather than calling themselves). In addition branded Med3 forms (which are used by GPs when completing sick notes for patients) with detachable slips to send to the Contact Centre were used from around the end of June 2004.

Sections 3.3 and 3.4 contain feedback and reflections on the marketing methods used.

1.2.4 Entering the trial
To enter the trial, potential clients called a central telephone Contact Centre, where:

- they were given a brief explanation of the trial;
- eligibility for the trial was checked;
- those eligible were asked a series of questions from which an ‘at risk’ score was determined, and those who scored above a threshold value were invited to enter the trial. The success of the screening tool in measuring risk of job loss is evaluated in Section 4.5;
- names and addresses of those ‘screened-in’ who wished to enter the trial were passed to NatCen for randomisation.

The role of the Contact Centre is covered in more detail in Section 4.1.
Screening (and randomisation) took place for a period of 21 months in total, from April 2003 to December 2004. During this time, a total of two thousand, eight hundred and forty-five people were screened and randomised into the JRRP trial. Section 3.2.2 contains more detail on the characteristics of those recruited.

1.2.5 Randomisation

Those who were screened-in and agreed to enter the trial were randomised to one of the four groups in equal numbers. This was done by a small team based at NatCen. The randomisation was carried out using ‘block randomisation’ separately for each pilot area, which ensured an exact 25 per cent allocation per group, both by area and over time. Randomisation occurred as quickly as possible after clients agreed to enter the trial, the maximum lag aiming to be 48 hours. The randomisation process is evaluated in Chapter 5.

The design of the trial and the different pathways that volunteers could take through it is summarised in Figure 1.1.

Figure 1.1 JRRP Trial Design

1.2.6 Notifying clients and providers

All clients were notified of the randomisation outcome by post, although those randomised to an intervention were not told at this stage to which of the three
groups they had been allocated. To minimise withdrawals, the letters were sent out on the same day as randomisation. Clients were also given a freephone number to call (at NatCen) for further information.

Service Providers were notified of anybody allocated to an intervention on the same day as the letter was sent. In most instances, such clients were then invited to an initial face-to-face meeting where they watched a short video that described the randomisation, and written consent procedure, were notified of their Intervention Group, given an explanation of what their intervention might look like, and asked to give written consent to receive interventions. Those giving written consent could then go straight to the assessment stage.

In two areas, the procedures for health intervention clients were different because the service was being provided by telephone; these clients were sent information about the consent procedures by post and asked to watch the video, sign the consent form and then post it back. However, these procedures changed half-way through the trial to become more similar to other areas, due to the higher levels of attrition which seemed to be resulting from this method.

The trial’s consent procedures are evaluated in Section 6.2.1.

1.2.7 The interventions

Those allocated to an Intervention Group and giving written consent were assessed and an individual Action Plan was drawn up. The interventions had to provide ‘boosted services’ (that is, services additional to those which could be accessed without the trial), be appropriate for the group to which the client was allocated, and adhere to the following ‘rules’:

- there were major differences between the health and workplace interventions (even if there were some common elements);
- elements that featured under one of these interventions for one provider should not be under the other for another provider.

The health intervention was defined in the following way:

- must be delivered away from the workplace;
- must deliver a treatment to the mind or body of the recipient;
- must not contact or seek to influence the employer or the workplace;
- could not be delivered by an Occupational Health Nurse;
- advice could only be about the health condition and focus on the physical body/mind.

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6 Those who refused consent at this stage had no further contact with providers, but were retained in the research sample for the Outcome Survey (see Section 1.3.2).
The workplace intervention was defined in the following way:

- could be delivered in any location;
- must be delivered by an appropriately qualified professional or organisation;
- could involve contact with the recipient’s employer;
- must focus on bringing about some degree of change within the individual’s workplace environment;
- advice could only be about the workplace or how people work.

The combined intervention could be any or all of the above.

Sections 6.4 and 6.5 give feedback on the design and delivery of the interventions.

### 1.2.8 The Service Providers

The four Service Providers and the areas they were responsible for are shown in Table 1.1.

**Table 1.1 JRRP Service Providers, areas and brand names**

<table>
<thead>
<tr>
<th>Lead organisation</th>
<th>Service name</th>
<th>Area</th>
<th>Area abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Glasgow, Public Health Department</td>
<td>HealthyReturn</td>
<td>Greater Glasgow</td>
<td>GL</td>
</tr>
<tr>
<td>Northumbria University</td>
<td>RouteBack</td>
<td>Newcastle &amp; Tyneside, Teesside</td>
<td>TY, TE</td>
</tr>
<tr>
<td>Sheffield Occupational Health Advisory Service (SOHAS)</td>
<td>WorkCare</td>
<td>Sheffield &amp; surrounding district</td>
<td>SH</td>
</tr>
<tr>
<td>Human Focus</td>
<td>WorkCare</td>
<td>Birmingham, West Kent</td>
<td>BI, WK</td>
</tr>
</tbody>
</table>

### 1.3 The JRRP evaluation

The evaluation of JRRP has two main strands: an evaluation of job retention services; and an evaluation of the trial itself. These are being evaluated via an impact assessment (including a cost-benefit analysis), a process evaluation and a Research Advice component. This report focuses on the findings from the latter strand.

#### 1.3.1 Evaluation objectives

The main objective of the evaluation of job retention services is to measure and compare the impact on return to work rates and job retention between the three Intervention Groups, and between the three groups and the Control Group. A successful outcome is defined as a return to work (to either the same job or a different one) of 16 hours or more for 13 consecutive weeks.
Return-to-work is the *primary* outcome for the trial and will be measured via a work history collected during an Outcome Survey which covers what clients were doing each week between going off sick and being interviewed (10-11 months later). Data has been collected on a large range of secondary outcomes, such as other work outcomes (for example, hours worked per week, attitudes to work, perceived barriers to work); health outcomes such as self-assessed general health, attitudes towards health, use of health services; and economic well-being of client households.

The evaluation of job retention services also aims to explore in detail clients’ experiences, and decision-making as they use the service and to witness change in their feelings, views and intentions as it occurs. It will provide an understanding of how clients use the service, what they think of it, and what type of help is more or less useful to them at different stages.

A further objective of this aspect of the evaluation is to examine the cost-effectiveness of the scheme and who gains and who loses from the services.

The main objective of the research into the *trial procedures* is to allow us to report on and respond to the following:

- that those entering the trial have understood the trial procedures, including the need for a Control Group (see Section 4.4);
- that the trial will have sufficient statistical power to determine the impact of the three interventions on return to work rates (see Sections 4.1 and 5.1.3);
- that the measures of impact derived from the trial are unbiased, or at least very close to unbiased (see Section 9.6.1);
- whether random assignment can be conducted satisfactorily in this context (see Section 5.6);
- how random assignment can be conducted most effectively in this context (see Section 5.6).

### 1.3.2 Evaluation design

*Research advice*

A key element of the evaluation was to observe the operation of the pilot to ensure that the procedures were working well and to help providers whenever possible on areas that related to the running of the trial (as opposed to delivering the interventions). Three Research Advisers from NatCen were engaged to give guidance to new staff on the consent procedures, talk over data collection and recording issues with providers and provide training.

The main issues were to see how well the screening tool worked; whether there were lessons in marketing that could be passed between providers; whether there were ways to ensure that the numbers not giving consent to treatment following
random assignment were minimised; and ensuring that inappropriate treatment, that is workplace treatment being given to the health group or vice versa (‘contamination’), was minimised.

The main elements of the Research Advice role were:

- site visits to Service Provider offices and the Contact Centre to observe working practices and to provide support and advice;
- analysis of routine administrative data to identify issues relating to sample numbers, withdrawals before giving consent and random assignment;
- small sample telephone interviews with clients to assess reasons for drop-out/non-participation;
- assessments of Action Plans and interventions to check adherence to the randomised allocation;
- ad hoc research to test the Contact Centre script;
- assessment of the screening tool via an early telephone survey to compare the deadweight rates\(^7\) of controls and those screened-out (known as the Survey of Screened-Outs and Controls or SoSOC).

Most of the material in this report has been derived from the Research Advice element of the evaluation, including the SoSOC survey. This short\(^8\) telephone survey was conducted among trial entrants who were randomised to the Control Group and people who had called up to join the trial but were screened-out as not being at risk of losing their job. The latter group did not include those who were ineligible to take part in the trial\(^9\).

The survey’s main aim was to provide an estimate of the deadweight rate of the trial, to give an early indication of the effectiveness of the screening tool (see Section 4.5). The deadweight measured by the survey is a return to work (of any length) amongst the controls at 28 weeks after first going off sick from work (28 weeks being when those still off sick become eligible to claim Incapacity Benefit). The survey also collects information on respondents’ experiences of entering the trial, which provides some of the data used in this report. More detail on this survey, including response rates, is given in Appendix A.

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\(^7\) The ‘deadweight rate’ refers to the proportion of clients who would have returned to work anyway, without any additional help from JRRP services.

\(^8\) The average length of interviews among the Control Group was 15 minutes and among the screened-outs, 20 minutes.

\(^9\) That is those who did not live and work within the designated areas, or who were within 18 months of planned retirement, or had not been off work for between six and 26 weeks, or did not work 16 or more hours per week.
**Impact assessment**

This element of the evaluation aims to measure the impact of the pilot via a face-to-face survey of all randomised clients, including the Control Group. This survey is called the Outcome Survey (OCS).

The impact assessment also includes a cost-benefit analysis to show the return on investment of the funds committed to the pilot intervention. Simply having the intended impact on clients is not enough, if that comes at great cost in terms of public funds that might have been used other ways. Once costs are considered, the net balance may not be favourable. The cost-benefit analysis will also inform the question of incidence and fairness that surround any public intervention: who gains and who loses from the scheme. The analysis will compare the costs of the interventions, derived from cost data collected directly from Service Providers and from the OCS, to their benefits in terms of any impact on return-to-work rates, use of health services and benefits.

**Process evaluation**

The components of this element are:

- a panel study of clients who were interviewed at regular intervals over a period of six months to collect ‘real time’ data about their experiences of the service.

- a series of focused, research question-led studies which explore:
  - the operation of the service;
  - how people return to work;
  - how GPs work with patients on sick leave;
  - employers policies and practises in dealing with employees on sick leave;
  - how the Control Group reached their outcomes and how they reacted to being in the trial.

**Evaluation database**

At the end of each monthly reporting period, every organisation involved (the Contact Centre, the randomisation team and each Service Provider), sent an extract of their data to be merged together centrally at ORC. The organisation contracted to create and manage the database. The merged extract became the Management Information and Evaluation Database, which contains screening information, details of services received from providers and outcomes for pilot participants.

10 There were some difficulties with the extracts sent to ORC. The Contact Centre data extracts did not contain all the necessary data items, and some providers experienced difficulties exporting their data. This was resolved when a new data capture system was set-up by SDA, the organisation contracted to do this.
The Management Information and Evaluation Database provides data for some sections of this report and will also feed into the process evaluation.

**Evaluation organisation**

The evaluation of JRRP is managed by officials from the Department for Work and Pensions’ (DWPs’) Disability and Work Division (DWD) in consultation with other colleagues from DWP strategy teams, Jobcentre Plus (who managed service delivery), DWP Contract Management Group and the Department of Health (DH). DWP had overall responsibility for the delivery of the pilot and the evaluation. The pilot is supervised by a project management board with officials from DWP, DH, the Health and Safety Executive, the Welsh Assembly and the Scottish Executive.

### 1.4 Outline of this report; other JRRP publications

This report aims to evaluate the operation of all aspects of this randomised controlled trial. As the trial’s methodology is innovative in UK social policy research, it is envisaged that this evaluation will inform decisions on the future use of random assignment and the design of any such trials. The report covers feasibility and set-up (Chapter 2), recruitment and marketing (Chapter 3), screening (Chapter 4), randomisation (Chapter 5), service delivery (Chapter 6), wind-down (Chapter 7), and management, communication and evaluation (Chapter 8). Conclusions and recommendations may be found in Chapter 9.

To preserve confidentiality, the information in some tables/figures has been anonymised. Provider names and pilot areas have been replaced with a symbol e.g. A, B, C and D. The providers/areas have been anonymised differently each time so that information across table/figures cannot be linked.

The methodological assessment contained in this report will inform the findings on the outcome of the trial, in terms of the impact of the interventions on return-to-work outcomes. However, this report does not contain any findings on outcomes, as these require careful analysis of the comprehensive data collected within the evaluation. Hence, the following reports are scheduled for publication early in 2006:11

- an impact report presenting quantitative analysis of participants’ characteristics, outcomes and impacts, together with cost-benefit analysis;
- an integrated report based on the participant (panel study and control group) and provider staff studies, presenting qualitative analysis of JRRP delivery and participants’ motivations and experiences.

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11 To receive notification when the reports are published and/or a copy of any of these reports, email Paul.Noakes@dwp.gsi.gov.uk. DWP research reports can also be found at www.dwp.gov.uk/asd/.
The following outputs from the evaluation have already been published:


2 Feasibility, implementation and set-up

This chapter describes the development of the trial design which evolved during the feasibility stage (Section 2.1). Design details and procedures were finalised during the implementation stage, and the service provision was then set-up (Section 2.2).

2.1 Feasibility stage

In September 1999, a joint group of the Government’s Advisory Committee on Disability Employment and Training, and the Disability Benefits Forum suggested that Government should consider the question of how best to assist people on sickness benefit to stay in or return to work through rehabilitation programmes or other forms of assistance. Subsequent cross-departmental discussions resulted in a proposal to attempt to test alternative approaches through a randomised controlled trial – from here the Job Retention and Rehabilitation Pilot (JRRP) was born.

The then Department for Education and Employment led on the early development of the trial. Within the Department decisions were made on the basic design elements, namely that the trial would be run as a four-way trial, with a workplace, health, and combined intervention, plus a Control Group; that the trial would be run in up to ten areas of the United Kingdom (UK), the exact number depending upon what those commissioned to provide the interventions could cover; and that the trial would be restricted to those off work sick for at least six weeks. The minimum length of six weeks was chosen as by this point, a large proportion (80 per cent) of those off sick would have already returned to work of their own accord. The Department also identified a broad number of issues that would need to be addressed before the trial could start. These included:

- the need to focus the trial on those most at risk of losing their jobs;

12 Based on the most recent Incapacity Benefit and Statutory Sick Pay data from 1995/6 supplied by DWP.
• the need for a reasonable and ethical means of handling the Control Group;
• the need to specify the exact nature of the interventions that would be delivered to each intervention group;
• the need to collect robust and reliable information on those randomised.

To this end DWP commissioned a series of reports:

• Nine potential Service Providers were asked to present an ‘ideas’ paper, setting out how they might market the trial to potential clients and the nature of the interventions that they would deliver.

• the National Centre for Social Research (NatCen), in collaboration with Michael White of the Policy Studies Institute, were commissioned to carry out an evaluation feasibility study, the intention being that the research team would work with the nine potential providers to flesh out the details of the trial design.

• A team from Glasgow University and Sheffield Occupational Health Advisory Service (SOHAS) were commissioned to develop a screening instrument that would allow those at most risk of losing their job to be identified (this instrument is discussed in detail in Section 4.2).

Early in the feasibility stage it became possible to enumerate the trial design elements that would need to be discussed and agreed upon. These were:

• Which elements of the trial would need to be standardised across all providers?
• Did the fact that JRRP was to be run as a randomised controlled trial restrict how providers market the trial? And if so, what were those restrictions?

• What would be the best means of ensuring that the Control Group did not get boosted services during the trial?

• How would potential clients get onto the trial?

• How would those not at risk of losing their jobs be screened-out?

• Who would carry out the randomisation, and how?

• How would consent to take part be collected?

• What procedures could be put into place to minimise the numbers who are randomised but who subsequently declined the intervention.

Discussions with the nine providers suggested that they had rather different views about marketing, and very different views about the content of the three interventions. The consensus view across the teams was, however, that the trial would still be legitimate if variation in marketing and the interventions was tolerated – within the overall constraints that each provider should market to the same client group, and that the services delivered under each intervention were compatible across providers (so that what was called a workplace intervention for one provider would not be a health intervention for another provider, and vice versa). So, for these reasons, it was
agreed that the areas to be standardised would be restricted to just five elements:

- screening;
- obtaining consent;
- randomisation;
- dealing with the Control Group;
- the data recorded per trial entrant.

Having reached this stage, the design-making process reduced to just two ‘big’ questions:

- How could the Control Group be prevented from getting boosted services?
- How best could standardisation be ensured?

In addressing the first question, providers were generally in agreement with the aspiration that, if at all possible, those randomised to the Control Group should not come into contact with the intervention case managers. The most persuasive argument for this was that, if no contact was made, there would be no ethical issues for case managers about refusing help to Control Group members.

Looking at the second question, three things drove the argument:

- for most people wishing to enter the trial, the first point of contact would inevitably be by telephone;
- the screening-tool questions could be administered over the telephone, and by non-clinical staff;
- consent to randomisation (although not to treatment) could, ethically, be collected over the phone.

Piecing all of this together, the JRRP model (as implemented) began to emerge. The main elements of the design concluded by the end of the feasibility stage were:

- Marketing would be carried out by Service Providers in their local areas.
- Those wishing to take part would make contact by telephone. To standardise the process, and to avoid contact between the providers and those subsequently randomised to the Control Group, the telephone Contact Centre would be set up as a separate entity. (This could have been one Contact Centre per area, but it was more efficient to set up just one nationally.)
- The telephone contact would cover eligibility checks, screening for risk, consent to randomisation, and (as was recommended at the end of the feasibility stage), randomisation.
- Those randomised to an intervention would be notified to the provider. The provider would then collect consent for treatment.
The notification of randomisation to providers would happen daily. This would minimise the time interval between screening and contact with the provider, the intention being to avoid losses because of ‘no-shows’.

Having ‘agreed’ on these main elements of the design with the nine providers (inevitably some of the nine were not entirely happy with the design), NatCen set out the details of the proposed design in a report to the Department for Work and Pensions (DWP) (Purdon et al., 2002). The nine providers supplied DWP with detailed proposals of how, and where, they would implement the trial taking into account the design agreed. From the nine, four were eventually selected for the trial.

It was valuable to have evaluators (NatCen) included in early discussions at the feasibility stage to advise and observe. This helped to ensure that the trial design was not compromised and that the evaluation design could be formulated to fit the procedures developed.

2.2 Implementation stage and setting-up the trial

Having gained ministerial approval for the trial, the next stage, post-feasibility, was the implementation stage. This was the stage during which the trial infrastructure was put into place and it took about nine months in total to complete (about three months more than originally anticipated). Representatives from DWP, Department of Health (DH) and NatCen worked with the providers during this stage.

Naturally, this produced some change in the details of the design between the feasibility stage and ‘go-live’. Two key ones were:

- The randomisation process was separated off from the screening process, with NatCen doing the randomisation. This meant that staff at the telephone contact centre were kept blind of the randomisation. The main advantage was that this ruled out any possibility (however remote) that the screening interviewer could influence the final allocation for an individual. A by-product, that was considered helpful, was that the screening interviewer could say that the randomisation was to be done by another team. This, we believe, helped to avoid any disappointment about the subsequent allocation being directed at the interviewer.

- To help standardise the full consent process for those allocated to an intervention, a short video was produced explaining the randomisation process, what would happen next, and emphasising that taking part in the trial was voluntary.

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13 The project was initially the responsibility of the Department for Education and Employment and subsequently DWP upon the creation of that department; the project was delivered by Jobcentre Plus within DWP.
But, in broad terms, the design agreed at the feasibility stage was the design ultimately implemented. During the implementation stage the following happened:

- the four Service Providers set up their operations, which in all cases involved recruiting staff and in several cases setting up new premises;
- the telephone screening centre was set up in Glasgow and staff recruited to it;
- the screening questionnaire to determine eligibility and a scoring system within the questionnaire calculating the level of risk was developed and programmed to computer-assisted telephone interview (CATI) format;
- the randomisation programme and procedures were written and tested;
- the video describing the consent procedures for those randomised to an intervention was produced; the consent forms and patient information sheets were designed.
- the ‘boundaries’ for the three intervention types were agreed upon;
- the Management Information System (MIS) was designed;
- protocols for information transfer between the various organisations were agreed on and then set up;
- the trial protocol was developed and (successfully) submitted to the West Midlands Multi-Research Ethics Committee (MREC) for ethical approval;
- provider and Contact Centre staff were trained in the trial procedures.

Although this is a very extensive list, what the implementation stage did not do was test out the procedures on real cases. Unsurprisingly, therefore, some of the systems were found to be less than watertight once the trial had started and changes had to be made on an on-going basis. For example, the CATI script used by the screening centre was not thoroughly tested before the pilot went live and some changes had to be made once it became apparent that some of the script was not being understood as intended by callers (see Section 4.3.1 for more detail). Changes also had to be made to the Management Information and Evaluation database (see Section 6.8) and a clearer protocol setting out the boundaries for the three interventions developed (see Sections 6.4 and 6.5).
Recruitment of volunteers for the trial was the first stage of the live-running of the pilot and a particularly crucial element. The trial could only succeed if enough people volunteered. The techniques that could be used to recruit people were affected by the nature of participation in the trial (voluntary) and the allocation to the four groups (by random assignment). In this chapter we consider Service Providers’ expectations about recruitment before the pilot started and compare this to what actually happened (Section 3.1). The characteristics of those who put themselves forward are discussed in Section 3.2.

The providers had to market the trial to the eligible population to persuade them to put themselves forward and Section 3.3 describes the marketing methods used and their effectiveness. How callers remembered hearing about the trial is also considered as a measure of the marketing’s effectiveness (Section 3.3.4). The last two sections present feedback from the providers on this aspect of the trial (Section 3.3.5) and our reflections about this stage of the pilot (Section 3.4).

The following sections use data collected during the screening interview at the Contact Centre from the Management Information and Evaluation Database and manual records, and from site visits to the providers conducted by the Research Advice team.

### 3.1 Analysis of recruitment

Before go-live, a recruitment prediction was developed by each provider based on their own expectations, seasonal variations and information about national sickness absence provided by the Department for Work and Pensions (DWP) on the total number claiming Statutory Sick Pay (SSP), the number of weeks of claiming SSP and whether claimants subsequently transferred to Incapacity Benefit (covering the period 1995/6\(^{14}\)). The eligible population was not identifiable in any official statistics so providers were required to make assumptions with this limited evidence to

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\(^{14}\) This is the most recent year of data available due to changes in SSP policy and the reduction in recording requirements for employers.
produce forecasts. Some of the predictions assumed that the numbers recruited each month would be fairly stable over time, but others were more fluid, showing relatively large fluctuations. All providers expected some fluctuations; two anticipated a gradual build-up over the initial months; most expected slower recruitment during April and the summer months of July/August; all expected slower recruitment during December/January.

Recruitment began on 31 March 2003 and continued for between 20 and 21 months. The final recruitment dates were determined independently for each provider based on their estimates of the length of time needed to ensure that the last trial entrants had a reasonable period to access treatment. Callers expressing an interest by the dates below were allowed a further week to decide whether they wished to participate and to call back for screening.

- WorkCare (SH): 23 November 2004,
- WorkCare (BI/WK): 11 December 2004,

These dates represent an extension of one or two months to the original recruitment period for most of the providers, which they agreed to in order to make up some of the shortfall in numbers.

Figure 3.1 shows the trial entrants actually recruited by each provider for each month of the trial period. The number recruited by each provider was relatively equal for the first five months. Thereafter, recruitment started to diverge as provider B continued to increase their rate of recruitment and provider C’s recruitment was slower, relative to other providers. As anticipated, recruitment for all Providers slackened in the two months to Christmas/New Year 2003, providers A and B being least affected. Recruitment picked up again throughout the spring and summer months of 2004, then decreased over the autumn months as marketing efforts were reduced in preparation for the end of recruitment.

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15 Screening and randomisation continued to operate on all days except the Bank Holidays during this period.
3.1.1 Comparison with predictions

The table below compares the total number of trial entrants with the predictions for each provider. Two providers recruited around half of the number predicted, the other two recruited between a quarter and a third of the total predicted. It should be acknowledged that the prediction was a particularly difficult task for this trial, although providers were advised that their assumptions appeared optimistic.

The main difference between actual and predicted recruitment in terms of the monthly fluctuations was that the expected low recruitment in January 2004 did not occur – numbers recruited were actually higher than December 2003 and February 2004. Providers met or came close to meeting their monthly predictions for a few months when their expectations had been particularly low, such as in August 2004.

Table 3.1 Comparison of trial entrants against predicted recruitment

<table>
<thead>
<tr>
<th>Provider</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predicted recruitment</td>
<td>2,133</td>
<td>2,132</td>
<td>1,953</td>
<td>1,333</td>
<td>7,552</td>
</tr>
<tr>
<td>Trial entrants</td>
<td>551</td>
<td>714</td>
<td>885</td>
<td>695</td>
<td>2,845</td>
</tr>
<tr>
<td>Entrants as % of predicted</td>
<td>26%</td>
<td>33%</td>
<td>45%</td>
<td>52%</td>
<td>38%</td>
</tr>
</tbody>
</table>
3.2 Analysis of callers and trial entrants

This analysis of the callers to the Contact Centre describes the characteristics of those who volunteered for the trial and the group of volunteers who were ineligible. Given the lack of knowledge about this population, it is important to have an understanding of the characteristics of the callers and particularly the trial entrants.

3.2.1 Caller eligibility

An analysis of all callers can only be conducted on calls received after 27 June 2004 because the Contact Centre did not record full information about every ineligible caller in the Management Information prior to this date. This may not be representative of the whole trial period but provides a reasonable estimate of the status of callers. A total of 1,350 volunteers called the Contact Centre between 28 June 2004 and the end of the recruitment. Eligibility for the trial was determined for 94 per cent of callers, around a third of whom (35 per cent) did not meet the eligibility criteria for joining. The reasons for their ineligibility are given in Table 3.2. Callers could be ineligible for more than one reason. Almost one out of every two callers found to be ineligible had been off sick for longer than 26 weeks and two out of every five were not employed. A third had not yet been off sick long enough and a quarter did not live or work in the right area. Relatively few were working fewer than 16 hours per week or were within 18 weeks of retirement.

Table 3.2 Reasons for ineligibility

<table>
<thead>
<tr>
<th>Reason</th>
<th>%*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off sick for more than 26 weeks</td>
<td>48</td>
</tr>
<tr>
<td>Not employed</td>
<td>41</td>
</tr>
<tr>
<td>Off sick for less than six weeks</td>
<td>33</td>
</tr>
<tr>
<td>Don’t live/work in pilot area</td>
<td>26</td>
</tr>
<tr>
<td>Working less than 16 hours per week</td>
<td>5</td>
</tr>
<tr>
<td>Within 18 weeks retirement</td>
<td>1</td>
</tr>
</tbody>
</table>

Base ** 377

* Column does not sum to 100 per cent because multiple reasons could apply

** n=57 missing

Of those who were eligible and taken through the full screening questionnaire, a relatively small proportion (six per cent) were not invited to join the trial because they were classified as not at risk of losing their job (‘screened-out’). The risk assessment is discussed in more detail in Section 4.2. Almost all the callers who were eligible and at risk then agreed to join the trial (99 per cent).

3.2.2 Caller characteristics

This section describes the characteristics of all trial entrants over the whole trial period (those who completed the screening questionnaire, and were eligible and at
risk of losing their job). Almost half came from two providers (split equally), almost a third from a third provider, and almost a fifth from the fourth provider. Where possible comparisons are made with population estimates for those in employment from the Labour Force Survey (LFS) winter 2003/4. Whilst this helps to put the profile of trial entrants into a wider context, it should be noted that these figures are not strictly comparable as the LFS covers the whole of the United Kingdom (UK).

Entrants were slightly more likely to be women (57 per cent), were concentrated between the ages of 30 to 59, and over nine in ten were White. The LFS shows that a majority of UK workers were male (54 per cent), and that they were younger than trial entrants on average (for example 14 per cent of UK workers were aged 16-24, whereas only three per cent of trial entrants were drawn from this group). One-quarter of trial entrants were single and two-thirds married or cohabiting. Almost two-fifths (38 per cent) had dependants to care for at home, mostly children under 16 years (Table 3.3).

Table 3.3  Demographic characteristics of trial entrants

<table>
<thead>
<tr>
<th>Gender</th>
<th>%</th>
<th>Ethnicity</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>43</td>
<td>White</td>
<td>92</td>
</tr>
<tr>
<td>Female</td>
<td>57</td>
<td>Black African</td>
<td>1</td>
</tr>
<tr>
<td>Age at screening</td>
<td></td>
<td>Black Caribbean</td>
<td>2</td>
</tr>
<tr>
<td>&lt;20 years</td>
<td>*</td>
<td>Bangladeshi/Pakistani/Indian</td>
<td>3</td>
</tr>
<tr>
<td>20-29 years</td>
<td>9</td>
<td>Chinese</td>
<td>*</td>
</tr>
<tr>
<td>30-39 years</td>
<td>27</td>
<td>Any other</td>
<td>2</td>
</tr>
<tr>
<td>40-49 years</td>
<td>32</td>
<td>Highest qualification</td>
<td></td>
</tr>
<tr>
<td>50-59 years</td>
<td>28</td>
<td>No Qualifications</td>
<td>20</td>
</tr>
<tr>
<td>60+ years</td>
<td>4</td>
<td>NVQ Level 1 or 2 or equivalent</td>
<td>34</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td>A levels, AS levels or equivalent</td>
<td>7</td>
</tr>
<tr>
<td>Single</td>
<td>23</td>
<td>NVQ Level 3 or equivalent</td>
<td>13</td>
</tr>
<tr>
<td>Married/Cohabiting</td>
<td>65</td>
<td>NVQ Levels 4-5 or equivalent</td>
<td>22</td>
</tr>
<tr>
<td>Separated/Widowed/Divorced</td>
<td>12</td>
<td>Professional Qualifications</td>
<td></td>
</tr>
<tr>
<td>Dependents to care for at home</td>
<td></td>
<td>Individual gross annual income band</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>38</td>
<td>Under £10,000</td>
<td>19</td>
</tr>
<tr>
<td>No</td>
<td>62</td>
<td>£10,000 - £20,000</td>
<td>53</td>
</tr>
<tr>
<td>Don't know</td>
<td>*</td>
<td>£20,000 - £30,000</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Over £30,000</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prefer not to say</td>
<td>1</td>
</tr>
</tbody>
</table>

One-fifth had no qualifications, one-third were qualified to NVQ level one or two, one-fifth to level three and a further fifth to level four or five. A fifth reported an annual personal income of less than £10,000, just over half placed their income in the range £10,000 to £20,000, and one-quarter reported higher incomes. Incomes appear to be lower than those of the working population (average gross annual...
earnings of all full-time employees is given as £22,724 by the LFS) but this may partly be explained by the fact that trial entrants did not all work full-time, that earnings may be lower than average in the trial areas and that income may have been reduced by sickness absence.

Just under three-quarters (74 per cent) had been working for 35 hours per week or more before their sickness absence. Most (94 per cent) were employees on permanent contracts and three per cent were self-employed. The proportion of self-employed entrants was much lower than among the UK population in work (13 per cent according to the LFS). This may be due to lower levels of self-employment in the trial areas, lower prevalence of health problems among the self-employed, or could indicate a failure to reach and/or attract this group onto the trial.

Around half of trial entrants worked in the public sector, and three-quarters for an organisation with 250 or more employees. The public sector is considerably over-represented compared to the UK population (28 per cent). Two-thirds of employees thought their supervisor/manager was understanding about their sick leave, and 84 per cent said they liked their job. Their occupations spanned a wide range (Table 3.4) from managers and senior officials (seven per cent) to elementary occupations (12 per cent). The largest category was associate professional and technical occupations (17 per cent) and the smallest was sales and customer service (six per cent). Compared to the UK population – measured by the LFS – managers and senior officials were under-represented (seven compared to 15 per cent) and personal services over-represented (14 compared to eight per cent). Again these differences could be due to the trial areas, differing levels of sickness absence between different occupational sectors, or due to the trial marketing being more or less likely to reach and appeal to certain groups.

<table>
<thead>
<tr>
<th>SOC major group</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managers and senior officials</td>
<td>7</td>
</tr>
<tr>
<td>Professional</td>
<td>9</td>
</tr>
<tr>
<td>Associate professional and technical</td>
<td>17</td>
</tr>
<tr>
<td>Administrative and secretarial</td>
<td>14</td>
</tr>
<tr>
<td>Skilled trades</td>
<td>9</td>
</tr>
<tr>
<td>Personal service</td>
<td>14</td>
</tr>
<tr>
<td>Sales and customer service</td>
<td>6</td>
</tr>
<tr>
<td>Process, plant and machine operatives</td>
<td>12</td>
</tr>
<tr>
<td>Elementary</td>
<td>12</td>
</tr>
</tbody>
</table>

Just over half (58 per cent) had been off sick between six and 12 weeks and 15 per cent for 20 weeks or more at the point of recruitment. Two-fifths had not taken any other period of sick leave in the last 12 months, and nine in ten had had no more
than six months sick leave in that time. Nearly half (44 per cent) had a musculo-skeletal condition, just over a third (35 per cent) a mental health condition, and 13 per cent a cardiovascular condition. This corresponds with an analysis found in the 2004 Chartered Institute of Personnel and Development report that observed that the most common cause of sickness absence was a minor illness followed by stress for non-manual workers and back pain for manual workers. There were no large differences in the length of time Job Retention and Rehabilitation Pilot (JRRP) trial entrants had spent off sick according to their health condition. Over half (55 per cent) had seen a doctor about anxiety/depression in the past and over a third (35 per cent) had suffered from panic attacks recently. Two-fifths had other reasons for being off sick, most commonly chronic pain, mobility problems, and loss of confidence. Four-fifths (80 per cent) were waiting for treatment.

Nearly half (43 per cent) did not know whether they would return to work after their current sick leave and around a fifth (21 per cent) said they felt able to. Almost half (47 per cent) did not know whether they would be able to do their job in six months time and just under two-fifths (39 per cent) thought they would be able to.

Some of these characteristics of trial entrants are given in more detail in Appendix B.

3.3 Description of marketing methods used and effectiveness

As discussed above, recruitment to the trial was not as high as originally estimated, thus marketing strategies were the subject of much discussion between DWP and Service Providers, and various new marketing initiatives were introduced during the course of the trial. Marketing was initially organised as local initiatives conducted by providers, but once it became clear that this was not delivering the numbers estimated, various central marketing initiatives were also implemented.

We present in this section the reflections of providers’ marketing staff on the process of marketing the trial, and the reasons that their predictions were not met, together with their suggestions for ensuring more successful recruitment in any future trial of this nature.

Providers used a wide variety of strategies to market the trial. Generally, they took a two-pronged approach, marketing both to gatekeepers such as general practitioners (GPs) and employers, and directly to potential volunteers. Because this was a research trial, the marketing was subject to various restrictions. For example:

- providers were not allowed to recruit people directly (to avoid contamination of the Control Group);
- GPs and employers were not able to refer people directly onto the trial, rather volunteers had to call the Contact Centre themselves;
- the marketing materials had to restrict the amount of information given about the potential treatments available to avoid raising expectations;
• the marketing materials also had to mention certain messages or straplines, for example:
  – benefits would not be affected by participation;
  – treatment could not be guaranteed;
  – the trial was outside the jurisdiction of GPs;
  – participation was free and voluntary;
  – the eligibility criteria;
  – the name of the sponsor of the trial.

Many of these restrictions were a condition of receiving ethical approval for the study. For example, direct referral by GPs and employers was not permitted due to concerns to prevent any coercion of potentially vulnerable people onto the trial. There were also concerns that direct referral might have lead to bias as GPs/employers might have been selective about who they referred.

As will become clear below, these constraints on what the marketing could say may have affected recruitment, as they severely limited all forms of advertisement. It is possible that any future programme without random assignment would find recruitment to be an easier task without these restrictions in place.

3.3.1 Marketing to GPs

Provider staff commented that getting access to those who could promote the trial was much more time-consuming than anticipated. In particular, GPs were seen as the most tricky group to engage and providers tried different methods to get them on board. Writing to them was not found to be effective nor was speaking at GPs’ conferences. One provider found that asking well in advance to speak at a Practice Learning Initiative helped to get GPs’ attention. Some marketing staff felt that GPs needed some kind of (perhaps monetary) incentive or benefit to persuade them to take notice of the trial. This is because there was no obvious reward for GPs in putting their patients forward; it could not be guaranteed that it would reduce the number of visits from these patients or that they would get better more quickly. Also, the emphasis on helping people return to work did not appeal to GPs as this was not always high on their list of priorities.

One suggestion to help sell the trial to GPs was to get local figureheads who were trusted and respected by GPs, to help market the trial. For example, key local GPs could help to attract a larger audience of GPs if they could be persuaded to speak at providers’ marketing events. Having a longer build-up period would have facilitated the identification of such figureheads.

One marketing strategy that received positive feedback from all, was having branded Med3 forms with detachable slips to send to the Contact Centre. These were circulated to GPs from around the end of June 2004. A volunteer could send
their details to the Contact Centre using a slip rather than calling themselves. The Centre would then get in touch to provide more information and take the volunteer through the screening if appropriate.

Generally the forms were felt to have been a useful marketing tool, as these official documents helped to persuade GPs that the pilot was authentic and ethical. However, producing the customised Med3 forms took a lot of work and negotiation and difficulties inherent in the production and distribution system made it a very lengthy and time consuming process. One advantage of using these forms as a recruitment aid is that this made it more difficult for GPs to influence who got to hear about the trial. One provider suspected that GPs were being selective in who they informed (for example, they might not suggest it to those they felt were not ready to return to work). However, as GPs have to complete a Med3 form for all who might be eligible, this ‘cherry-picking’ could not take place.

3.3.2 Marketing to employers

Similar challenges were encountered when selling the trial to employers. It was not always obvious who was the right person to approach, as this varied and was not always the Human Resources or Occupational Health Department. It was not easy to get employers to see the benefits to themselves of putting employees forward for the trial. A common reaction was that they were already providing support to employees off sick, so including them in the research was not necessary. This required some careful thought about how to market the trial without implying that employers were not providing (adequate) support. Some providers found it useful to draw on research findings to demonstrate to employers the effectiveness of early intervention in helping people return to work.

With hindsight, some providers felt that they should have started marketing the trial to employers earlier, in particular to Chief Executives. One provider sent letters to Chief Executives in their area part way through the trial, setting out the business case for their services and found that this led to additional applications even from firms that had been resistant to taking part. Another lesson learned was that it pays to be prescriptive to employers about how to cascade information about the trial, as this saves them work in having to think about what to do.

Another factor which affected the long-term effectiveness of marketing through employers was whether those they had referred actually ended up getting the service. Marketing staff received feedback from employers who thought that the people they had referred were not getting anything, therefore there was no point to refer people. They were not necessarily aware that people could be ineligible, in the Control Group or allocated to an Intervention Group that could not offer the type of help the employer may have envisaged.

Several staff commented that targeting employers was not the best way to recruit a representative sample for a trial of this kind. Certain types of employers seemed to be more amenable to promoting the pilot, in particular larger ones (although one provider found large employers to be the hardest to persuade). It was felt that GPs
might be a better source of volunteers as their patients are drawn from the full range of employers. Furthermore, providers suspected that employers might have prioritised those whom they felt could benefit most or whom the employer was most keen to return to work. Callers who heard about the trial from their employer were more likely to be female, married or cohabiting, and work for a public firm with at least 250 employees, than those who heard from their GP. However, these differences could be due to either GPs’ or employers’ practices in informing people or to other factors (such as the type of employers targeted).

Another disadvantage of recruiting via employers is that coercion to take part is possible. Some providers and the Contact Centre suspected that this was sometimes happening, but it was difficult to do anything about it due to the risk of identifying the employee to the employer. However, preliminary findings from the Outcome Survey (Stratford et al., 2005) suggest that, thankfully, coercion into the trial by employers was rare (only one per cent said that their employer had instructed them to take part).

### 3.3.3 Marketing to volunteers

Providers used a range of methods to reach volunteers, including leaflets (to which freepost slips were added from autumn 2003 for volunteers to return to the Contact Centre to call them) and posters, advertisements in local newspapers and radio, and recruitment via GPs and employers as described above.

The challenges faced in marketing the trial to participants were somewhat different. Restrictions on what the marketing could say were perceived as barriers to operating the marketing in a proper commercial manner. Marketing staff felt that the messages they were obliged to put out were not immediately appealing or applicable to clients. It was also felt to be unhelpful that the marketing had to focus on the fact that people had to be at risk of losing their job to be eligible to take part. Staff felt that most people do not realise they are at risk, so this would have put them off applying, and that the focus should have been instead on the length of time they needed to have been off work.

Another aspect of the prescribed marketing content which some found unhelpful was having to mention that benefits would not be affected by participation. Staff cited anecdotal evidence that this merely served to raise suspicions that benefits might be affected and put potential volunteers off. The prescriptive nature of the marketing content also created problems for marketing staff as it introduced delays and bureaucracy into the marketing process. They felt that the process of getting materials checked by DWP/Department of Health (DH) was onerous and took a long time.

Once it became clear that providers were struggling to recruit the numbers envisaged, DWP commissioned research from the National Centre for Social Research (NatCen) and Andrew Irving Associates. This involved in-depth interviews with 48 eligible non-participants, 24 employers and the providers in five of the JRRP
areas, as well as 15 telephone interviews with people randomised to the intervention groups. The resulting recommendations led to a number of new marketing initiatives, led by DWP/DH. These included a trial of direct marketing at GP surgeries, conducted during April 2004 by Field Advisers from an independent organisation, who attempted to promote the trial directly to those attending. They were given restricted information to give to interested people, and encourage them to call the Contact Centre.

It was difficult for providers to judge whether this had an effect on recruitment (there was no evidence from the monthly recruitment figures of any large effect). Some did not think that it was very effective as there was only a low chance of meeting someone eligible for the trial at a GP surgery. Feedback from the advisers suggested that on the whole, interest from the public was low and they did not give out many leaflets. Also, some of those who were eligible were not interested as they did not wish to return to work. However, one provider said that they had received positive feedback from GP surgeries as it relieved GPs of the responsibility of explaining the trial to patients.

Providers also felt that the usefulness of the direct marketing strategy was constrained by the fact that direct appointments with clients could not be made as they had to be referred via the Contact Centre. They also questioned whether GP surgeries were the best setting to conduct such marketing, as they are not very private. One provider was interested in doing their own direct marketing, but felt that supermarkets and shopping centres would be better venues. However, another provider felt that the direct marketing had been successful in certain areas, and continued to do their own direct marketing once the field advisers stopped work.

Another initiative on the part of DWP/DH was to involve the Central Office of Information (COI), in designing and co-ordinating a more centralised marketing strategy. A mailshot of employers was also conducted through the COI to raise awareness. Some providers commented on noticeable benefits, whilst others were concerned about substantial under-coverage of known employers.

Reviewing the effectiveness of the marketing was difficult but providers benefited from weekly feedback from the Contact Centre about the sources of marketing remembered by callers and the relative proportions of ineligible and eligible volunteers from each source. It was sometimes possible for the effectiveness to be seen directly, for example, an immediate but short-lived increase in callers was seen when radio advertisements were run.

### 3.3.4 How callers had heard about the trial

This section considers the impact of the marketing methods described above. Callers to the Contact Centre were asked how they heard about the trial before their eligibility was assessed. Table 3.5 shows the marketing sources remembered by all volunteers who were eligible and joined the trial.
The distribution of the marketing methods reflects the focus of provider marketing activity, with GPs being the principal source. Employers and leaflets also played an important part in raising awareness of the pilot. A small proportion of people heard about it through a friend or relative, other organisations, or through radio and newspaper advertisements.

After the implementation of the new screening script (see Section 4.3), further categories were added. Occupational Health Adviser/Nurse was the most common source previously recorded as ‘other’, making up 15 per cent of this category across all areas, and as much as 31 per cent in area vi. Hospitals/medical centres and other healthcare professionals were mentioned by four and three per cent respectively. A few trial entrants cited other organisations or the Internet. Med3 slips made the most impact in areas ii and iii. The receipt of both Med3 and freepost of slips by the Contact Centre is shown in Figure 3.2.

Table 3.5 How trial entrants heard about the trial, by area

<table>
<thead>
<tr>
<th>Marketing Source</th>
<th>Area*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>i</td>
</tr>
<tr>
<td>GP</td>
<td>%</td>
</tr>
<tr>
<td>Leaflet</td>
<td>20</td>
</tr>
<tr>
<td>Employer</td>
<td>16</td>
</tr>
<tr>
<td>Other</td>
<td>22</td>
</tr>
<tr>
<td>Friend/relative</td>
<td>5</td>
</tr>
<tr>
<td>Poster</td>
<td>4</td>
</tr>
<tr>
<td>Newspaper</td>
<td>2</td>
</tr>
<tr>
<td>Radio advert</td>
<td>3</td>
</tr>
<tr>
<td>TV advert</td>
<td>-</td>
</tr>
</tbody>
</table>

Base 695 346 205 364 521 714 2,845

* Columns do not sum to 100 per cent because up to three marketing sources could be mentioned.

Note that ‘leaflet’ also includes getting in touch with the Contact Centre via a freepost slip during the last six months of live running. This may have affected the accuracy of the relative importance of the marketing sources.
Compared to trial entrants, ineligible callers were more likely to remember hearing about the trial from their GP, and by leaflet, but less likely to have heard from their employer or an Occupational Health Adviser/Nurse. The marketing sources for ineligible callers were only available for calls received after 27 June 2004, which may not represent the whole trial period because the marketing developed over time, but can be compared with trial entrants for the same period. From this comparison, it seems that employers and Occupational Health Advisers were better sources of eligible callers than were GPs (Table 3.6).

3.3.5 Improvements to marketing suggested by provider staff

Marketing staff had clear ideas as to how the marketing and therefore recruitment could be improved for any similar future trial. Many felt that one reason that recruitment fell short of estimates is that the original estimates were not informed by reliable knowledge of the size and nature of the target population (although providers were asked to conduct research locally to provide this information). With hindsight, they perceived the need for more initial research to provide more information about where clients are located, their characteristics, and whether they would be likely to volunteer. One suggestion was to find out how many sick notes were written in a sample of GP practices and for what length of time, to estimate how many might have been eligible. Lacking such research, staff felt that it was unclear who comprised the market, and therefore, to whom they were aiming the

17 No data is available for the final month of recruitment – December 2004 – when fewer than 30 volunteers joined.
marketing. For a future trial of this kind, they suggested that the marketing be built in to the very early strategic design of the trial.

Table 3.6  How trial entrants and ineligible callers heard about the trial

<table>
<thead>
<tr>
<th>Marketing Source</th>
<th>Trial entrants %</th>
<th>Ineligible callers %</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP</td>
<td>48</td>
<td>56</td>
</tr>
<tr>
<td>Leaflet</td>
<td>33</td>
<td>37</td>
</tr>
<tr>
<td>Employer</td>
<td>25</td>
<td>12</td>
</tr>
<tr>
<td>Occupational Health Adviser/Nurse</td>
<td>15</td>
<td>7</td>
</tr>
<tr>
<td>Hospital or medical centre</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Friend/relative</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Poster</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Newspaper</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Other healthcare professional</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Jobcentre</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Internet</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Other organisation e.g. CAB, Trade Union</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Radio advert</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>TV advert</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>

Base 748 572

* Columns do not sum to 100 per cent because up to three marketing sources could be mentioned

Recruitment was felt to have been especially difficult at the start of the trial. Providers felt that there needed to be a longer build-up period for marketing the JRRP trial (suggestions ranged from three months to a year before go-live) in order to build up awareness, understanding and enthusiasm, both among gatekeepers such as GPs and employers, potential participants and internally at DWP and DH. The marketing teams would have liked to have been involved in this early ‘pump-priming’. Thus they would have needed to be in place well before the trial started, which was not the case for all providers.

Although initially all providers were keen to conduct local marketing (as they hoped for eventual business advantage from the pilots), by the end of the trial, marketing staff were of the view that greater involvement of DWP and/or DH in the marketing at the start of the trial would have improved its efficacy (for example, a central marketing team put in place before go-live). One reason for suggesting this was that a letter sent from DWP/DH to GPs produced a very good response as it gave the trial added credibility. Staff felt that more of this kind of involvement was desirable and that simply having the DWP/DH logos on marketing materials was not sufficient to give the kudos needed.
Some providers held launch events just before go-live (March 2003) for GPs and employers. This was seen as a worthwhile exercise, and the attendance of a DWP/DH representative was appreciated. However, they felt that this would have been even better if a high profile representative could have attended, such as a minister. Again, this would have helped to raise the profile and credibility of the trial among a key audience.

Providers were given a marketing allocation based on the costs for marketing provided in their bids. However, some felt that these estimates turned out to be insufficient to achieve what was desired. A larger budget would have enabled them to use higher profile marketing such as more press and radio advertisements and more national marketing such as daytime TV. This would have been helpful to increase awareness among the client group as the key to successful marketing is repetition and reinforcement of messages (‘saturation’), preferably by different sources/media. A higher budget would also have enabled more marketing staff to be employed, which would have relieved the heavy workload on existing staff.

Although most providers had been keen to use their own brand name, with hindsight, some felt that the same name should have been used in all areas. This would have avoided the confusion experienced by national employers trying to promote the trial in more than one area.

One provider commented that recruitment could have been increased had they (and/or the Contact Centre) been able to contact potential recruits directly. They felt that those off sick who are possibly depressed lack the motivation to make a phone call. They would have liked to be able for example, to ask employers for lists of eligible employees who could be contacted directly. A similar suggestion from another provider was that GPs should have been allowed to directly refer people onto the trial, rather than only being able to inform them about the trial. This is apparently standard practice in medical randomised controlled trials so was not seen to have ethical problems. These strategies would have helped to prevent any under-representation of clients with mental health disorders, who it was felt, would have been more likely to take part if they had not needed to be so proactive to join.

Communication was another area singled out for improvement by providers. Marketing staff commented that there were too many interested parties at DWP, DH and the Central Office of Information (COI), which made communication difficult and resulted in long delays (communication in general is dealt with in more detail in Section 8.2). They would therefore suggest that for future trials, there be a dedicated communications and marketing contact with marketing knowledge and experience within DWP.

A final suggestion was to increase the length of the trial as soon as it was realised that recruitment was not going to meet the targets. A 12 month extension would have made up a large proportion of the shortfall, although the extra numbers and resulting improvement in detectable impact might not have been sufficient to make the extra time and financial investment worthwhile.
3.4 Reflections on recruitment and marketing

The experience of this trial confirms the crucial importance of the recruitment process. JRRP followed in the footsteps of many other trials, which have commonly recruited fewer volunteers than predicted. This caused some staff to become disheartened in the early months and may have affected how they perceived the trial. However, most staff did remain motivated to give the best possible service to the reduced number of volunteers entering the trial.

3.4.1 Improving recruitment predictions

More accurate predictions may have been possible if more resources had been channelled into this element. Although providers had been asked to do local research on which to base their predictions, their resources were limited and many had relied too heavily on relatively dated national information. More research into the population, perhaps through focus groups and conducted centrally, could have increased knowledge and perhaps produced more realistic expectations.

3.4.2 Impact of recruitment procedures on sample profile

The recruitment processes had a variety of implications for the profile of those recruited to the trial. The procedures required the volunteers to be motivated, which may have reduced recruitment by acting as an informal screener – those who thought they were not at risk of losing their job may not have been motivated to put themselves forward (also see Section 4.6.2).

The marketing influenced who called the Contact Centre and ultimately the composition of the trial sample. The marketing was developed independently by each area (although there was some collaboration during the trial), and as a result, was focused differently (in terms of content and method) in each area. This is likely to have affected the number of and type of callers. The characteristics of those who had heard from their GP and their employer differed to some extent. Callers who heard about the trial from their employer were more likely to be female, white, married or cohabiting, and work for a public organisation with at least 250 employees compared to those who heard from their GP. Callers who heard from an Occupational Health Advisor/Nurse had similar characteristics to those who heard from their employer. Some differences may have been due to different practices in informing people, or due to the fact that the marketing was often focused where the highest returns were expected. For example, larger (and public) employers were targeted because they were easier to access and could provide more potential recruits. It is not clear that the methods used in any one area were completely successful in saturating the market at any one point in time, and hence the trial sample characteristics are likely to reflect the marketing conducted.

Whilst all of the marketing materials included information about the eligibility criteria, as a relatively high proportion of callers were ineligible because they had been off sick for less than six or more than 26 weeks, or were not employed. It is not clear whether the eligibility criteria had been ignored deliberately by callers or whether they had simply not registered them.
3.4.3 Voluntary nature of recruitment

The recruitment design and procedures were shaped by the voluntary nature of participation. If the trial had been mandatory for a given population, or recruited through an official list, the procedures may have been very different.

The trial had to be voluntary, both because this was the only way to identify participants and because of ethical concerns about coercing those who are sick or injured and therefore potentially vulnerable. It must be recognised that the voluntary nature of the trial is likely to have affected the composition of trial entrants. Volunteering requires a degree of motivation that the providers believed would be low for some key sub-groups such as those with mental health problems, who may as a result be under-represented. Providers were also concerned that trial entrants may not fully represent the wider population of all those off sick if people did not put themselves forward because they perceived themselves to be too ill to return to work or did not see themselves as eligible if they were waiting for treatment.

Providers suggested mandatory referral through GPs to alleviate this problem, although they acknowledged some of the disadvantages that could bring, such as GPs ‘cherry picking’ or the risk that money would be wasted treating people who do not intend to return to work. Also it might have been difficult to collect the type of baseline data that this trial collected during screening.

3.4.4 Improvements to the marketing

The credibility of the brand name and the legitimacy of the pilot as a whole were seen to be important factors affecting the success of the marketing. The brand names were new so that awareness and credibility had to be built up from scratch. When the backing of DWP and DH was made more explicit to gatekeepers like GPs and employers, for example through a centralised mail out, it increased the credibility of the pilot (although providers did have concerns that linking the trial with DWP could deter participants because of a fear of losing benefits).

The marketing is likely to have been more effective if it had begun before the trial started to build-up awareness in advance. Recruitment may have been higher if central initiatives such as employer mail outs, field advisers and branded Med3 forms had begun earlier and been co-ordinated more effectively. Although most providers chose not to share a brand name, a national name would have simplified central marketing initiatives and made it easier for national employers to circulate information internally.

The restrictions on its content (described at the start of Section 3.3) was believed to have impacted on the success of the marketing. The mandatory strap lines included mention of the eligibility criteria, the fact the trial was free and voluntary, and the sponsor of the trial. Given their mandatory nature and the need for provider staff to feel confident in their marketing, it would have been beneficial to test the effects of the strap lines (in terms of making sure people understood and were not put off by...
them). There were strong reasons for restricting the amount of information about the potential treatments available (because the treatments differed by intervention which could not be predicted, and to reduce contamination across groups in particular the Control Group), but it reduced the effectiveness of the marketing because it made it harder to convince potential volunteers that there would be treatments that they wanted.

The marketing restricted direct contact between Provider staff and potential volunteers to reduce the risk of contamination. This restriction should be reconsidered for future trials faced with similar recruitment issues. A higher risk of contamination might be acceptable if the method delivered significantly more trial entrants.

For this population and trial design the most effective and ethical recruitment appears to have been through GPs compared to employers because there was more scepticism from employers, the right contact was harder to identify, it was harder to prevent “cherry picking” and more instances of coercion were noted by Providers from volunteers who had heard about the trial from their employers (although this was rare as measured by the Outcome Survey). The central initiatives (branded Med3 forms for GP practices and mailing employers) were seen as a useful tool for accessing so called referral organisations like GPs and employers who were otherwise seen as difficult to access. However the recruitment may have been improved by considering how these types of organisation act as gatekeepers for the population, and whether processes focusing on the gatekeepers could have been put in place from the beginning.

When a trial is totally reliant on marketing to draw in the required number of volunteers the resources used for this should reflect its relative importance. There may have been a case for planning more of the marketing centrally to avoid duplicating processes and learning locally. The burden of risk for the recruitment through marketing was placed squarely with the Providers. It would have been possible and may have improved recruitment for other more specialised organisations to have conducted the marketing, although it could be risky to break the link between recruitment and service provision; a Service Provider will be driven by the number of entrants but there is no direct impact upon a separate recruitment organisation which may not have the level of motivation to achieve the levels required.
4 Screening tool and Contact Centre

Volunteers interested in joining the trial phoned a Contact Centre and were given a screening interview to determine their eligibility (Section 4.1). The development of the screening tool is described in Section 4.2. This chapter examines some research conducted on the quality of the screening in terms of its design (Section 4.3) and its effectiveness (Section 4.5). Volunteers also provided feedback about their perceptions of the screening process (Section 4.4). Finally, we consider all of the evidence to reflect upon the process, including the eligibility criteria (Section 4.6).

4.1 Role of the Contact Centre and screening

The central Contact Centre gave volunteers a brief explanation of the trial and asked a set of questions to check their eligibility and assess their risk of losing their job or business. Volunteers were also asked to provide contact details and some baseline information such as demographic characteristics. Information that uniquely identified each volunteer was used to prevent previous volunteers from entering the pilot again before completing their participation. Callers gave their verbal consent for the research team to use the information for the study, and if they were invited to join the trial, they were asked to give verbal consent to be randomised.

A standard script explaining the key aspects of the pilot was read out alongside the questions. This formed part of the ethical obligations in that it confirmed that participants were not being coerced into the trial, that they understood this to be a randomised controlled trial and were given enough information to be able to give informed consent to randomisation. The Contact Centre also acted as an information point for individuals and organisations wanting to find out more about the pilot.

The assessment of risk conducted during the call acted as a screen to reduce the number of people in the trial who would have returned to work whether or not they received an intervention. The aim was to reduce the resources which providers devoted to people who did not need any help to return to work. This was necessary
because the pilot sought to intervene early in the period of sickness absence even though it was known that in the first weeks, a high proportion would return to work as a result of their own actions. Either the trial needed to recruit more volunteers to compensate for the high proportion who would return on their own (known as the ‘deadweight’), or some of the ‘deadweight’ had to be identified and not invited to take part (‘screened-out’).

The screening also increased the power of the impact estimates to allow an effective measure of relative net impact of each of the three types of intervention with a smaller sample size than would otherwise be required. Additionally, if screening could be shown to identify in advance those who would benefit most from additional interventions, it could provide lessons about the cost effective future implementation of any proven intervention. Thus a screening tool was developed to predict volunteers’ risk of losing their job or business as a result of their sickness absence. Those who scored below a threshold measure of risk (and thus were most at risk) were invited to take part in the trial.

The screening tool was implemented as a CATI (Computer Assisted Telephone Interview) questionnaire, administered by trained advisers at the Contact Centre. If requested the questionnaire was administered at the volunteer’s home, or through a translator. Both of these were uncommon with no more than ten callers requiring a translator and no more than 20 having a home visit.

The tool was administered by a central organisation to ensure a standard experience for callers, and due to the practical advantages of setting up just a single Contact Centre (for example fewer staff to train, and making it easier to ensure standard implementation of the tool and to conduct monitoring). A further important reason for using a separate organisation was to minimise ‘contamination’ of the Control Group (that is, affecting their behaviour in any way) by preventing direct contact with providers.

Providers expressed a number of concerns that the Contact Centre might have acted as a barrier to entry to the pilot. Firstly, the volunteer had to be comfortable using the telephone and choose to make the call. Secondly, the screening questionnaire had to be undertaken before they could join the trial. Finally, providers were concerned that the screening questions themselves would be threatening and act as a deterrent. However callers were not aware of the questions in advance and could only be put off by this during the call. Only two per cent of callers who phoned to join the trial (after 27 June 2004) refused to complete the screening process, which suggests that this caused, at most, very little deterrence.

Some indirect benefits of the Contact Centre were mentioned by providers, such as adding credibility to the trial entry process, and simplifying the self-referral procedure because the eligibility rules were applied by the Contact Centre staff. An unexpected benefit was trial entrants using the Contact Centre as a go-between to keep in touch with provider staff when they had lost their contact details.
4.2 Development of the screening tool

The screening tool was developed by a team from Glasgow University and Sheffield Occupational Health Advisory Service specifically for Job Retention and Rehabilitation Pilot (JRRP). A thorough literature review was undertaken to examine tools and scales predicting sickness absence, risk of job loss, chronicity of health condition and characteristics associated with return to work (see Peters et al., 2003). No existing tool or scale was found to be applicable for the pilot. The most robust variables were selected for further testing and translated into a questionnaire.

Firstly, the questionnaire was delivered to 216 people who attended general practitioners (GPs) surgeries for renewal of their medical certificate or who visited occupational physicians, and who had been on sickness absence for between six and 18 weeks. Of these, 139 were successfully followed up around three months later to assess their employment outcome (whether they had returned to their job, were still on sick leave, had changed employment or were unemployed). The second study was a retrospective study using the occupational health records of 1,350 employees of a Scottish county council who had attended an occupational health provider in the past five years.

The data from these studies was used to build a predictive model with an outcome variable of ‘failure to return to work after 12 to 15 weeks’. An expert panel of 15\(^{18}\) met to evaluate the results and a set of 13 variables that had the strongest association with failure to return to work were identified for inclusion in the final screening questionnaire. Of these, the five strongest predictors of failure to return to work were re-entered into the model to produce the risk score algorithm. The five predictors were:

- **Q1** ‘Do you think that you will be able to return to work after your current sick leave?’ Yes/No/Don’t know
- **Q2** ‘Do you believe that, from the standpoint of your health you will be able to do your present job in six months’ time?’ Yes/No/Don’t know
- **Q3** ‘How long have you been off work sick?’ (number of weeks)
- **Q4** ‘Can I have your date of birth?’ (derived age in years)
- **Q5** ‘Are you currently waiting for a consultation or treatment for your current problem?’ Yes/No/Don’t know

The coefficients associated with each possible response to each predictor are given in Table 4.1. By far the most influential question is whether the individual thinks they will be able to return to work after their current sick leave.

\(^{18}\) The expert panel consisted of GPs, occupational health and public health specialists, social researchers and medical statisticians, representatives from the Department of Health and representatives from the Department for Work and Pensions (DWP) strategy division, the analytical division and Corporate Medical Group.
Table 4.1 Risk score algorithm coefficients

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Response</th>
<th>Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Yes</td>
<td>4.527561153</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>3.11712554</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>Q2</td>
<td>Yes</td>
<td>1.903013171</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>0.920450249</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>Q3</td>
<td>6-10 weeks</td>
<td>1.040070127</td>
</tr>
<tr>
<td></td>
<td>11-20 weeks</td>
<td>0.527827324</td>
</tr>
<tr>
<td></td>
<td>21-26 weeks</td>
<td>-0.473305299</td>
</tr>
<tr>
<td>Q4</td>
<td>Up to 35 years</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>36-45 years</td>
<td>0.268727324</td>
</tr>
<tr>
<td></td>
<td>46-55 years</td>
<td>0.086444126</td>
</tr>
<tr>
<td></td>
<td>56-65 years</td>
<td>-0.580935458</td>
</tr>
<tr>
<td></td>
<td>66+ years</td>
<td>-1.832284965</td>
</tr>
<tr>
<td>Q5</td>
<td>Yes</td>
<td>-0.861155106</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>Intercept</td>
<td></td>
<td>-5.366763369</td>
</tr>
</tbody>
</table>

The algorithm works by applying the coefficient estimates to the characteristics of each potential participant, the sum of which is the risk score value. A cut off of 0.78 was determined by looking at the distribution of the predicted values in the model. Volunteers achieving a score greater than the cut off were not considered at risk of job loss for the purposes of the screening tool being tested in the field, and were ‘screened out’.

4.3 Assessment of the screening tool

This section describes two pieces of research which were undertaken by the Research Advice team to test that the screening script was effectively communicating the key messages and to monitor the way in which the screening tool was being administered.

4.3.1 Screening script research

Once the trial had been up and running for a number of months, the Research Advice team undertook a small ad hoc research project as part of an investigation into non-participation in JRRP. This involved 15 telephone interviews with people randomised to an intervention group and revealed that the screening process was failing to communicate key messages about the trial as effectively as it might. This had implications for the whole principle of ‘informed consent’ which underpinned the design of the pilot.
The Research Advisers then conducted a second small-scale study to test out what improvements could be made to the screening tool to ensure that key messages were communicated more effectively. An additional aim was to understand how callers interpreted, and responded to, the questions used to determine eligibility for the trial and the ‘degree of risk’ of losing their job. This second study was intended to provide specific, rather than comprehensive findings, within a short time scale. To facilitate sample recruitment, simpler eligibility criteria were stipulated for volunteers for the study than for the pilot itself. Volunteers were required to:

- be in employment, or self-employed, for 16 plus hours per week;
- have had a period off work sick for three weeks or more within the last three months;
- live and work in non-pilot areas to avoid any risk of them applying to join the trial at any stage.

Other variables such as age, gender and employment were not specified but the achieved sample of ten volunteers was well balanced in terms of these characteristics. Further details can be found in Appendix C.

The interviews used cognitive and qualitative interviewing techniques to focus on three key aspects of the Contact Centre script:

- the explanation of the research trial;
- the questions designed to elicit callers’ eligibility and ‘degree of risk’ of losing their job;
- callers’ response to being told the outcome of the screening process: whether they had been assessed as being eligible or ineligible to take part in the trial.

The Contact Centre script was revised in conjunction with DWP as a result of the findings from this study. The new tool was first used on 28 June 2004. The most substantial change was the revision of the script read out to callers that described the pilot and key messages enabling volunteers to give informed consent to participate. Some of the wording was altered and the text was split up to make it easier for the caller to remember and ask questions about it. The screening questions largely remained the same to maintain consistency in the risk scoring. The ordering of some questions was revised to improve the flow, and on screen guidance was added for the Contact Centre advisers.

### 4.3.2 Observing screening interviews

Screening interviews were recorded and used to observe how the screening was conducted. An analysis was conducted of a random sample of 28 recordings from the first ten months of live running, covering all screening outcomes and all pilot areas. Further details of the selected calls can be found in Appendix C.
Overall the recordings gave the impression that the Contact Centre advisers were providing a valuable service and giving a good first impression about the pilot to callers. Generally they were sensitive, caring and interested in the callers. However the recordings identified the need for some refresher training. Three main issues were identified:

- Firstly the screening questions were not always read out exactly as the script dictated. There were a number of questions that were awkward, for example because the question wording was too formal or was not understood easily, which explains some of the changes that the advisers were making. The desire to build rapport with the caller may have also been a reason for diverging from the question text. This was problematic if the changed wording led to a different interpretation of the question.

- The advisers were adding extra descriptions to the standard script explaining about the pilot. Extra descriptions were often given if the caller had asked for information or had questions at the beginning of the call that had been answered by reading sections of the standard text which were later repeated during the screening interview. This highlighted an urgent need for a revision of the script (as described in the previous section).

- The final issue was a gradual increase in inaccurate information being provided. The advisers were restricted to generic information about the pilot and the interventions until they paid visits to provider premises after eight months of live running. The aim of the visits was to inform the advisers about the specific provider situations to enable them to answer questions from callers, such as whether the site was central and easily accessible by public transport. Confusion about the exact nature of the pilot process/provision and the differences between the pilot areas appears to have occurred mostly after these visits. It must be noted that the visits did help advisers to provide correct information to many callers who are likely to have benefited from the first hand knowledge of the provider environment. However, it did also lead to an increase in incorrect information as the advisers sometimes got the providers confused and gave information that related to the wrong provider.

The recordings also provided some feedback about how the screening was working as part of the trial process. There was little evidence that any aspects of the screening were off-putting for callers. Callers who were found to be ineligible or were screened-out did not exhibit adverse reactions in general. There was some evidence that potentially contaminatory information was being given out, such as specific medical treatments being cited as examples of the health intervention, but this was not extensive.

It had been hoped that listening to a selection of calls since June 2004 (when the script changes were made) would have provided some feedback about the effects of the changes made, but unfortunately the recordings cannot be accessed.
4.3.3 Screening data capture

At the start of the trial, the IT structure set up for the screening had not been implemented fully. The main problems were that callers who were not calling for the first time were not automatically checked against previous callers to ensure they were identified, and secondly some of the data captured during the screening interview were not stored permanently. In June 2004 a new web-based system was implemented to correct these problems, as well as implementing the new script as described above.

Beyond some initial teething problems, the changes appeared to improve the screening processes, in that:

- volunteers who called on more than one occasion were identified more often;
- full data, including extra items, were recorded to facilitate a more complete analysis of the callers and their characteristics;
- question responses were retained when a screening was halted but continued at a later point (to avoid repeating questions);
- fewer IT disruptions were experienced during screening interviews;
- and fewer clients were delayed between screening and randomisation due to IT problems.

4.4 Feedback from SoSOC respondents on screening

Feedback on the screening was gathered from Survey of Screened-Outs and Controls (SoSOC) respondents who remembered phoning the Contact Centre to find out about the project. Most (97 per cent of controls and 94 per cent of screened-outs) remembered this call. Those who remembered getting an explanation when they called the Contact Centre were asked for their views on this. Control Group respondents were asked about their reactions to the outcome of randomisation and whether they had understood the voluntary nature of the trial.

Most respondents who remembered being given an explanation of the project had a good understanding of the trial processes, including a good awareness of the existence of a Control Group. A high proportion (85 per cent of controls and 78 per cent of screened-outs) felt that the explanation of the trial was clear. In addition, most (89 per cent of controls and 85 per cent of screened-outs) said that it was clear that there was a chance that they might not receive any extra help. However, a minority of respondents (18 per cent, 32 per cent), in particular screened-outs, said that they would have liked to have had more information about the project.

The screening itself was also clear for most respondents, who found the screening questions clear and easy to understand (88 per cent of controls and 85 per cent of screened-outs). Most of those in the Control Group who remembered the screening interview said they understood that they had a choice as to whether to continue taking part in the project (86 per cent).
Table 4.2  SoSOC respondents’ understanding of the trial procedures

<table>
<thead>
<tr>
<th>When you heard the explanation of the project ...</th>
<th>Control</th>
<th>Screened-out</th>
</tr>
</thead>
<tbody>
<tr>
<td>...was the explanation clear and easy to understand?</td>
<td>85</td>
<td>78</td>
</tr>
<tr>
<td>...was it clear that there was a chance you might NOT receive any extra help to return to work?</td>
<td>89</td>
<td>85</td>
</tr>
<tr>
<td>...did you think you would be eligible for the service?</td>
<td>74</td>
<td>51</td>
</tr>
<tr>
<td>...were you given all the information that you wanted?</td>
<td>82</td>
<td>68</td>
</tr>
<tr>
<td>...did you think that the types of services offered would help you get back to work?</td>
<td>86</td>
<td>69</td>
</tr>
</tbody>
</table>

Unweighted base (respondents who remember the explanation) 486 109

The results of screening were anticipated by more Control Group than screened-out respondents. Most controls (74 per cent) thought they would be eligible for the project when they heard the explanation, and 78 per cent thought that they would be asked to take part after answering the questions. This compares with around half (51 per cent) of screened-outs who thought they were eligible, and 55 per cent who thought they would be asked to take part. It is difficult to tell whether these differences really reflect what the respective groups felt at the time of screening or whether they represent post-rationalisation after the results of screening were known.

Table 4.3  SoSOC respondents’ understanding of the screening process

<table>
<thead>
<tr>
<th>When you answered those questions...</th>
<th>Control</th>
<th>Screened-out</th>
</tr>
</thead>
<tbody>
<tr>
<td>% saying yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>...did you find them clear and easy to understand?</td>
<td>88</td>
<td>85</td>
</tr>
<tr>
<td>...did you think you would be asked to take part in the project?</td>
<td>78</td>
<td>55</td>
</tr>
<tr>
<td>...did you think you had a choice whether to continue taking part in the project?</td>
<td>86</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Unweighted Base (respondents who remember the screening) 518 119

4.5  Effectiveness of the screening tool

The screening tool was designed to reduce the proportion of people entering the trial who would have returned to work without an intervention – the deadweight – to 50 per cent or less. Volunteers with the least risk of losing their job were identified.
through a risk score calculated from their screening responses (ranging from zero to one). Testing prior to the tool’s implementation suggested that not inviting those with a score above 0.78 to join the trial would reduce the deadweight of trial entrants to 50 per cent or less. Six per cent of those assessed during live-running had a score over the threshold.

**Table 4.4  Distribution of risk score**

<table>
<thead>
<tr>
<th>Risk score</th>
<th>Percentage of volunteers assessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most at risk (&lt;0.1)</td>
<td>40</td>
</tr>
<tr>
<td>0.1 - &lt;0.2</td>
<td>13</td>
</tr>
<tr>
<td>0.2 - &lt;0.3</td>
<td>9</td>
</tr>
<tr>
<td>0.3 - &lt;0.4</td>
<td>8</td>
</tr>
<tr>
<td>0.4 - &lt;0.5</td>
<td>8</td>
</tr>
<tr>
<td>0.5 - &lt;0.6</td>
<td>6</td>
</tr>
<tr>
<td>0.6 - &lt;0.7</td>
<td>7</td>
</tr>
<tr>
<td>0.7 - 0.78</td>
<td>4</td>
</tr>
<tr>
<td>&gt;0.78 - &lt;0.8</td>
<td>1</td>
</tr>
<tr>
<td>0.8 - &lt;0.9</td>
<td>4</td>
</tr>
<tr>
<td>Least at risk (0.9+)</td>
<td>1</td>
</tr>
</tbody>
</table>

*Base 3,032*

Table 4.4 shows the distribution of the score for all of the assessed volunteers, over half of whom had a low score (<0.2). The rest were fairly evenly distributed over the remaining range of scores, gradually decreasing from nine per cent to four per cent as risk decreased until there were relatively few with the highest scores (one per cent with a score of 0.9 or more).

The tool was designed to allow it to be altered if necessary during the live running of the pilot. Changes would have been welcomed if the tool was found to be screening out too many/few volunteers and not achieving the desired level of deadweight. Either the threshold could have been moved or the algorithm used in the risk score calculation could have been changed. Unfortunately, the lower than anticipated number of trial entrants and a smaller than anticipated proportion being screened-out meant that an early indication of the effectiveness of the tool was not possible. As a result no changes were made. However it would be possible to conduct an exercise in the future to test the effect of changing the algorithm retrospectively (using different variables or altering the threshold). The rest of this section provides more details about how the effectiveness of the tool was measured.

### 4.5.1  Definition and measurement of deadweight

The Control Group was used as a representative sample of trial entrants for the measurement of the trial’s deadweight rate. Deadweight is defined as the number of trial entrants who would have returned to work whether or not they received an
intervention. In principle, the true deadweight rate for this trial is the proportion of the Control Group joining the trial after six weeks of sickness absence, who then had a period of continuous work of 13 weeks or more, at some point between six and 41 weeks after their sickness absence started. This deadweight rate will be measured by the Outcome Survey, which took place 44 weeks after the start of the sickness absence spell for each trial entrant (or 48 weeks for those entering the trial after 22 weeks of sickness absence). Since this was a rolling survey there would not be a final measure of deadweight until autumn 2005. We were keen to be able to adjust the sensitivity of the screening tool early in the trial, therefore an approximate measure was necessary. The approximation of the true ‘deadweight rate’ was measured as the proportion of the Control Group that had returned to work (full- or part-time) 28 weeks after first going off sick. The measurement was obtained through a short survey of the Control Group and screened-out volunteers (SOSOC).

This approximate measure was arrived at by calculating the latest point at which a person in the Control Group could start an employment spell that would mark them as a deadweight case (i.e. the latest they could have returned to work within the six to 41 week window for a continuous period of 13 weeks or more). This point is 28 weeks after the start of sickness absence. Assuming that all respondents who start work will continue to work for 13 weeks, the observed activity at 28 weeks is sufficient to approximate the deadweight rate. The timing of this survey in relation to time off sick and entry to the trial is illustrated in Figure 4.1 below.

**Figure 4.1 Timing of deadweight measurement**

![Diagram showing the timing of deadweight measurement](image)

19 The period needed to allow time for the intervention as well as 13 weeks back at work.
A prospective element was also included in the survey to take account of respondents’ expectations of their activity at week 41. If there was no data collected on expectations, the activity at 28 weeks is extrapolated to the 41st week. This estimate of activity at 41 weeks is likely to give an over-estimate of deadweight but is a useful indication of the higher end of the range of deadweight estimates. An indication of the lowest deadweight rate can be obtained by comparing the return to work and job loss rates between the trial entrants and screened-out groups by the length of their sickness absence. These comparisons will give an indication of the accuracy of the approximate measure. The SoSOC approximation includes everybody regardless of their length of absence when screened for the trial to achieve a sufficient sample size.

The data have been weighted to try to reduce any bias introduced by differential response to the survey. Characteristics recorded during screening were used to estimate a non-response model, and the predicted values from the model were used as weights. Further details can be found in Appendix D.

### 4.5.2 Deadweight estimate

Activity at 28 weeks\(^{20}\) is given in Table 4.5, separately for the Control Group and the group screened-out, and weighted to account for non-response. Respondents who reported being on paid annual leave, were re-coded to their pre-holiday status (either paid work or sick leave). The table shows that the deadweight rate at 28 weeks for the Control Group is 41 per cent. The 95 per cent confidence interval for this estimate is 37 to 45 per cent. Even a more conservative estimate including paid work of less than 16 hours would increase the deadweight rate to only 45 per cent.

Thus the screening tool met its target; deadweight is comfortably below the 50 per cent level assumed in designing the trial. A comparison of the deadweight rates of the Control Group and those screened-out also provides evidence of the success of the screening tool. Seven out of every 10 of the screened-out group were in paid work (16+ hours) at week 28 (95 per cent confidence interval of 62 to 78 per cent). The difference between the rates of the two groups is relatively large and is statistically different from zero (at the one per cent level). The screened-out group’s rate of return-to-work is much higher than the threshold of 50 per cent.

Of further interest is that only three per cent of the screened-out cases had stopped working at the time of the interview, compared to eight per cent of the Control Group. It is reassuring that the clients that were most at risk of losing their job were more likely to be identified for inclusion in the trial.

\(^{20}\) The history only covered week 26/27 in some cases. The 28th week has been imputed as the same as the previous week’s activity.
Table 4.5  Activity 28 weeks after going off sick, by screening outcome

<table>
<thead>
<tr>
<th>Activity</th>
<th>Control Group</th>
<th>Screened-out</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paid work (16+ hours)</td>
<td>41</td>
<td>70</td>
</tr>
<tr>
<td>Paid work (&lt;16 hours)</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Sick leave</td>
<td>47</td>
<td>25</td>
</tr>
<tr>
<td>Not working</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td><strong>Unweighted base</strong></td>
<td><strong>539</strong></td>
<td><strong>132</strong></td>
</tr>
</tbody>
</table>

The comparison above uses weighted data from the survey respondents. However non-respondents were asked about their current activity when they refused to take part in the survey. An activity was recorded for 40 per cent of Control Group non-respondents and 34 per cent of screened-out non-respondents. A comparison of their activities using unweighted data for all respondents and non-respondents with known activity gives similar results to the comparison above.

Finally, a projection of activity 41 weeks after going off sick (as described in the previous section) finds 58 per cent of the Control Group in full-time work, compared to 83 per cent of screened-outs. As mentioned, this is likely to be an overestimate of deadweight but provides an upper estimate.

4.5.3  Characteristics of screened-out callers

The characteristics of the sub-group of callers who were screened-out as not at risk of losing their job differed from trial entrants with respect to the risk score characteristics as designed (with a higher proportion of 40-49 year olds, shorter periods off sick, being less likely to be waiting for treatment, and with most feeling able to return to work after their current sick leave or return to their job in six months time). They also differed according to other characteristics. Compared to trial entrants, callers who were screened-out were significantly more likely to be:

- living in the Birmingham pilot area and less likely to be in the Tyneside area;
- white (97 per cent);
- educated to NVQ level four or five (29 per cent);
- receiving a higher income: almost a fifth (18 per cent) reported an annual income of less than £10,000, less than half (44 per cent) placed their income in the range £10,000 to £20,000, and over a third (37 per cent) reported higher incomes;
- caring for dependants (46 per cent);
- off sick for a shorter period over the last 12 months (82 per cent were off sick for up to three months in the last year), and for the current period to be their only time off sick (47 per cent);
free from suffering with panic attacks recently (74 per cent);
working for a public rather than a private company (62 per cent);
working for a medium size company with 50-249 employees (16 per cent);
in a job where the supervisor/manager was understanding about their sick leave (77 per cent);
enjoying their job (90 per cent).

This suggests that it could be worthwhile testing the effect of changing the algorithm retrospectively (using the variables above).

4.6 Reflections

Overall the Contact Centre and screening worked well within the trial design. The service provided by the Contact Centre was generally good with the staff interacting well with callers. The rapport built up by the advisers was an important element of the success of the screening. Using the telephone for contact did not seem to generate many difficulties although it is impossible to know whether there was a significant group of people who did not put themselves forward because having to use the telephone was a barrier. Once telephone contact had been made, the caller could request a face-to-face meeting, although very few did so.

The advantages of centralising the process appeared to outweigh the disadvantages although it is difficult to judge the extent of discontent with the set-up for people who did not call the Contact Centre. Although we do not have the evidence to judge whether recruitment could have been increased if contact had been face-to-face, it was widely believed that it would be easier to persuade volunteers of the benefits of the trial through face-to-face contact. However, it is likely that making the first contact over the telephone would be easier for most volunteers even if face-to-face contact was desirable.

4.6.1 Screening tool

Some aspects of the screening process differed from the original design. The screening interview was longer than originally planned, and callers sometimes called more than once to complete it. In addition only a relatively small percentage of eligible callers were screened-out by the tool. This implies that the trial might have been able to rely completely on the informal screening process whereby callers who do not consider themselves at risk of losing their job would not put themselves forward to join the trial.

Regardless of the level of recruitment, the tool met its target of reducing the deadweight in the trial entrants to no more than 50 per cent. Future research projects may find the screening tool useful for other applications although the choice of questions and the risk score algorithm were chosen for this (specific) population of interest. Whilst the potential was not exploited, it was sensible to have
included the capacity to alter the sensitivity of the tool. The flexibility was used to alter the eligibility criteria (widen the pilot area geographies).

The advisers delivering the screening did not know which of the questions contributed to the risk assessment but it was easy for them to identify themes linked with being screened-out (some of which were coincidental). The assumption had been that it was better to make the assessment blind to the callers and the advisers to minimise the temptation to influence responses. However if advisers did try to influence the callers, for example towards being screened in if they felt they deserved to be included, then unknown biases may have been introduced.

The assessment was also blind to the providers. This created some difficulties for them in that they were not party to any of the screening information and therefore had to ask clients for many details which they had already given at screening. Whilst it was important that the assessment remained blind to the callers, allowing providers access to this information might have helped to create a greater degree of trust between the organisations involved in the pilot.

It became apparent that some callers had not taken on board some of the key elements of the design (such as participation being voluntary). Some calls indicated that employers had pressurised people to join the trial. Reiterating these key elements was an important part of informing the callers to allow them to make an informed choice about whether to give consent or not.

Implementation

Before implementation the tool needed more thorough testing with respect to question design and order. It was unfortunate that an improved version of the standard script was only developed after problems during live running. The IT system also needed more thorough testing before go-live to ensure that all aspects had been implemented. Whilst fortunately the impact of the failure to identify previous callers was small, it could have been more substantial. It is difficult to assess the impact of the lost data. (The implications of the failure to identify previous callers for the randomisation are discussed in the next chapter.)

More detailed training of the Contact Centre advisers by the Research Advisers before go-live would have improved the standardisation of the screening interview from the start of live running. This would have helped to ensure that from the start, Contact Centre advisers always read out questions exactly, did not add explanations of their own, and read out the response categories appropriately.

The visits to providers may have increased the Contact Centre advisers’ commitment to the pilot and there will have been benefits from being able to reassure callers when they were unsure and had questions. The visits resulted in stronger links between the Contact Centre and the providers, which had been relatively separate at the beginning. This was advantageous for easing communication to give feedback about the marketing but had the potential to introduce problems because
of the opportunity to share inappropriate information. This ‘information role’ was not wholly successful because:

- it increased the chances of contamination when one of the aims of having a separate Contact Centre was to reduce contamination; and

- incorrect information was sometimes given to callers which raised expectations needlessly.

4.6.2 Eligibility criteria

All but one aspect of the eligibility criteria were simple rules (such as working at least 16 hours per week), which were publicised through the marketing and so were transparent for volunteers. The transparency and simplicity allowed ‘self-screening’ which is likely to have reduced the volume of enquiries at the Contact Centre from ineligible people. It also made it easy to explain to callers why they were not eligible, with the exception of the risk assessment. The risk assessment introduced some difficulties for the marketing because the degree of risk and therefore whether the trial could be accessed could not be determined in advance. This was perceived as difficult to explain by organisations such as employers and GPs who wanted to recommend the pilot to potential volunteers.

Some of the eligibility rules had been modified during the implementation phase (prior to the start of the pilot) after discussions with the providers about their implications. Further possible modifications came to light during live running (although none were made). A widely held view among provider staff was that the earlier clients were reached after going off sick, the more likely it would be that they would return to work. There was a suggestion that clients could have been recruited before six weeks of sick leave, as this would prevent the development of secondary problems, such as depression, and loss of motivation and confidence to return to work. The disadvantage would be the higher proportion of deadweight although to an extent the screening tool should have been able to identify and screen them out.

Provider staff also indicated that the aim of intervening early could have been hindered due to the requirement to be off sick for at least six weeks ‘continuously’, since sick leave can be intermittent. For example, the services may have been able to help a person who had been off sick for four weeks, back at work for two days, then off for two weeks, but this person would not be eligible for another four weeks.

It was also suggested that the requirement not to be within 18 weeks of planned retirement could have been extended to two years, since it was found that there can be a considerable incentive for clients to take medical retirement within this period and their motivation to return to work could be low.

The geographical criteria – needing to live and work within particular areas – was seen as restrictive by some providers, although there was evidence that having larger areas served by a single central office would not be in the interests of some trial entrants, due to the increased distances involved. These criteria were flexible to
some degree since some of the areas were expanded during live running in response to the lower than anticipated recruitment.

The most complex aspect of the eligibility criteria, being at risk of losing your job, was perceived as a disincentive to volunteering. Providers did not believe that people could accurately assess their own risk, as clients’ perceived level of risk did not always match the case manager’s assessment. This was included in the marketing information, which may have deterred people who could have benefited because they did not perceive themselves to be at risk. It is likely that omitting this information from the marketing would have altered the composition of the volunteers putting themselves forward. Also the Contact Centre advisers found it uncomfortable explaining to volunteers who said that their employer was threatening to sack them that they were deemed to have a low risk of losing their job.

Volunteers’ motivation to return to work was not considered explicitly in the criteria. However, upon joining the trial it became apparent that some participants did not want to return to work, because they disliked their job or a more appealing alternative was likely to become available. Also, the criteria did not use the volunteer’s health condition as a basis for exclusion. One provider questioned whether participants with long-term conditions were appropriate for the pilot. These were characteristics put forward to consider for the future.
5 Randomisation

The randomisation process was conducted by the National Centre for Social Research (NatCen), an organisation independent of the Contact Centre and Service Providers. Basic details about each trial entrant were transferred from the Contact Centre to the randomisation team. The process is described in detail in Section 5.1 and the distribution of trial entrants over the four groups is presented in Section 5.1.2. The random allocation was generated by a computerised algorithm (see Section 5.1.1). The details about each entrant allocated to an Intervention Group were then transferred immediately to the relevant provider, and a letter sent to the entrant. The level of withdrawal after randomisation, but before giving written consent, is discussed in Section 5.1.3. A letter was also sent to each entrant allocated to the Control Group (their details were not transferred to the provider). An information line was set up to support trial entrants after randomisation (Section 5.2). The randomisation process ran smoothly throughout most of the period, but the few problems encountered are discussed in Section 5.3. Both pilot staff (Section 5.4) and volunteers' (Section 5.5) understanding of and reactions to randomisation are given before Section 5.6 concludes with our reflections about the process.

This chapter mainly draws on data from the randomisation program database and Research Advice site visits to providers. Withdrawal from the trial was analysed using data from the Management Information and Evaluation Database.

5.1 Randomisation process

Twice daily the Contact Centre transferred to the randomisation team a file containing the basic details of callers who had been screened into the trial and consented to randomisation by secure encrypted email. Time limits were set to reduce the delay between screening and being contacted by the provider – they aimed to contact those allocated to an Intervention Group no later than the day after they had been screened. Thus the file received by 12.00 would be randomised before the end of the working day, and the file received by 17.30 would be randomised the following working day before noon.
Upon receipt of the file it would be loaded into the specially designed program to be processed. The processing conducted a number of checks on the data, allocated the trial entrants to one of the groups, produced a letter for each entrant to notify them of the allocation result, and produced a separate file for each provider containing all of the entrants allocated to Intervention Groups. A file would be created even if there were no entrants to be transferred to confirm that this was the case. Immediately after processing, each file was encrypted manually, emailed to the relevant provider, and the notification letters were printed and sent out (see Appendix E).

The Intervention Group letter did not specify the exact allocation, simply saying that clients had been allocated to a group that would receive extra help. This was because differential withdrawal had been anticipated from each group; it was expected that clients would be less likely to anticipate the potential benefits from workplace interventions relative to health interventions. Delaying the notification of the exact allocation to a point where the provider could provide more details about the possible interventions was designed to prevent withdrawal through ignorance. One of the aims of the trial procedures was to reduce withdrawal between randomisation and giving written consent as much as possible, to preserve the balance of the clients allocated between groups that was achieved through randomisation.

After receiving a client’s details, the provider would hold an initial meeting to tell them their exact allocation group and discuss what was available to them. The notification letters included a freephone number to call if clients wanted to discuss their allocation or anything else related to the research (see Section 5.2).

Care was taken to ensure that screening, randomisation and contact with providers continued through the whole period of recruitment (except Bank Holidays), for example continuing between Christmas and New Year. A contingency plan was developed to use if electronic transfers failed and would delay trial entrants more than a previously agreed acceptable period.

### 5.1.1 Random allocation

The randomisation algorithm was devised to randomly allocate trial entrants into one of four groups, treating each pilot area separately. Block randomisation was used to prevent each area receiving a large number of clients in any one group over a short time period. Firstly the block sizes were selected as multiples of the number of allocation groups – four, eight, and 12. A block size of four contained one of each group, size eight contained two of each group and so forth. The program first randomly selected a block size, then randomly selected the order of the allocations within the block, for example health, control, combined, workplace. For this example the first trial entrant would be allocated to the health group, the second to the Control Group etc. Once all of the allocations in the block have been used the process starts again by randomly selecting a new block size. The randomisation program had been tested in advance to ensure that the algorithm was working as designed.
The random aspects of the block randomisation ensure that it is difficult to predict the next allocation, even knowing the previous allocations. Furthermore for this trial, the allocation outcomes were not communicated to the Contact Centre and they were not aware of past allocations so the potential for the advisers to alter the order in which they submitted trial entrants for randomisation (to affect their allocation) was very remote. In addition, the automatic nature of the transfer between the two organisations reduced the chances of this happening.

The program produced a summary report of the random allocations on a weekly basis which was used to monitor the allocations. The program also stored all of the allocations ever conducted in an Access database, which was interrogated on a monthly basis for monitoring purposes. A number of checks were built-in to prevent randomisation being conducted inappropriately (see Appendix F).

5.1.2 Trial entrants randomised

Administrative data was monitored weekly to check that the randomisation software allocated an equal number of trial entrants to each of the four groups within each area. The total allocations by the end of recruitment are shown in Table 5.1. Each column in the table shows almost exactly equal numbers in each group, which confirms that the allocation met the design requirements. Data collected during screening was used to compare the characteristics of each group. There is some variation across groups but no substantial differences. The numbers in each group are not exactly equal because at any point in time each area is unlikely to be at the end of a block of allocations.

Six further random allocations occurred that have been removed from the table:

- One volunteer living outside the pilot area was erroneously randomised, and not subsequently transferred to the provider;

- Two trial entrants were screened a second time before successfully completing their first spell on the trial, but were successfully identified and re-allocated to same group to complete their participation (one workplace and one control case in area xvii);

- One trial entrant was screened a second time before successfully completing their first spell on the trial, and was not identified until after screening. This person was erroneously randomised and not re-allocated to the same group, but was not subsequently transferred to the provider (Control Group case in area xvii);

- One trial entrant was transferred for randomisation before their consent was received and erroneously randomised, not subsequently transferred to the provider (Control Group case in area xviii);

- One trial entrant was transferred for randomisation twice, their erroneous randomisation was identified after their transfer, and they were not subsequently transferred to the provider (Health group case in area xvii).
Table 5.1  Group allocations of trial entrants, by area

<table>
<thead>
<tr>
<th>Randomisation Group</th>
<th>Area</th>
<th>xiii</th>
<th>xiv</th>
<th>xv</th>
<th>xvi</th>
<th>xvii</th>
<th>xviii</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>51</td>
<td>86</td>
<td>91</td>
<td>130</td>
<td>173</td>
<td>179</td>
<td>710</td>
<td></td>
</tr>
<tr>
<td>Work</td>
<td>52</td>
<td>87</td>
<td>91</td>
<td>130</td>
<td>174</td>
<td>178</td>
<td>712</td>
<td></td>
</tr>
<tr>
<td>Combined</td>
<td>51</td>
<td>86</td>
<td>91</td>
<td>131</td>
<td>175</td>
<td>179</td>
<td>713</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>51</td>
<td>87</td>
<td>91</td>
<td>130</td>
<td>173</td>
<td>178</td>
<td>710</td>
<td></td>
</tr>
<tr>
<td>Base (all randomised)</td>
<td>205</td>
<td>346</td>
<td>364</td>
<td>521</td>
<td>695</td>
<td>714</td>
<td>2845</td>
<td></td>
</tr>
</tbody>
</table>

5.1.3  Post-randomisation attrition

Some trial entrants withdrew from the trial after they had been allocated to an Intervention Group but before they gave consent to receive the intervention. By definition the Control Group could not withdraw. The level of withdrawal, or attrition, at this stage was 18 per cent overall, but the levels differed by randomisation group and area. Generally the highest levels of attrition are seen for those randomised to the workplace group and the lowest for the health group. A fuller analysis of attrition will be conducted within the main impact evaluation to assess the implications for the estimate of the impact of the interventions.

The level of attrition varied by area from four to 29 per cent. The rate of attrition is likely to have been influenced by many factors including the inflow rate of entrants, the intensity and speed of initial contact made with trial entrants, the ability of provider staff to describe how their service could help them and the nature of the service provided (for example, transport arrangements). It should be noted that not all of these withdrawals were chosen by the client. Preliminary data from the Outcome Survey suggests that about a fifth of respondents who left the pilot early did so simply because the provider had either not contacted them or had not offered them any treatment (Stratford et al., 2005).

Table 5.2  Attrition, by area and Intervention Group

<table>
<thead>
<tr>
<th>Intervention Group</th>
<th>xix %</th>
<th>xx %</th>
<th>xxi %</th>
<th>xxii %</th>
<th>xxiii %</th>
<th>xxiv %</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>6</td>
<td>8</td>
<td>10</td>
<td>17</td>
<td>20</td>
<td>22</td>
<td>14</td>
</tr>
<tr>
<td>Work</td>
<td>6</td>
<td>16</td>
<td>11</td>
<td>25</td>
<td>33</td>
<td>35</td>
<td>22</td>
</tr>
<tr>
<td>Combined</td>
<td>0</td>
<td>9</td>
<td>12</td>
<td>19</td>
<td>24</td>
<td>31</td>
<td>17</td>
</tr>
<tr>
<td>All</td>
<td>4</td>
<td>11</td>
<td>11</td>
<td>20</td>
<td>26</td>
<td>29</td>
<td>18</td>
</tr>
<tr>
<td>Base</td>
<td>154</td>
<td>536</td>
<td>259</td>
<td>522</td>
<td>273</td>
<td>391</td>
<td>2135</td>
</tr>
</tbody>
</table>
5.2 Information line

A freephone information line number was given to all those randomised (in the notification letter). It was intended to give the Control Group access to some support that would not contaminate them (that is, would not suggest actions they would not have thought of otherwise). The team taking the calls were trained to advise a client to see their general practitioner (GP) or employer if they pushed for advice. The number was also given to clients allocated to the Intervention Groups so that they had a contact that was independent of their provider. One of the providers highlighted the benefits from having an independent body liaising with the Control Group to encourage the feeling that they were an integral part of the trial.

Up to the end of December 2004 when recruitment had finished, 127 participants had used the information line. More calls were received from Intervention Groups than from the Control Group (86 and 33 clients respectively). The main reason for calling among Intervention Group participants related to contacting their provider, whereas Control Group participants tended to call because they were upset or disappointed about their group allocation. Further details can be found in Appendix G.

The volume of calls was lower than anticipated. This could be interpreted positively possibly indicating that there were only a few participants who experienced difficulties with the pilot. However, it is thought that some calls that might have been directed to the information line were actually made to the Contact Centre. (The Contact Centre number was prominent in the marketing literature and on the information sheet handed to Intervention Group participants when they first met their provider.) Participants may have contacted the Contact Centre because they did not want to leave a message on the information line answer machine; or because they had built up a good rapport with the Contact Centre advisers; or perhaps because they saw the trial processes as seamless and were not aware that different organisations were responsible for different aspects of the trial.

5.3 Problems encountered

The Contact Centre, randomisation team and Service Providers implemented IT systems and data transfer procedures that allowed data to be transferred quickly and securely. A testing procedure was implemented before the pilot started and repeated intermittently when changes to data templates were made. The testing eliminated most problems.

Further information can be found in Appendix F, which details the checks added to the program as a result of the problems below:

- **File content** – in the first weeks simple errors such as missing or impossible values in data fields were found. Human error allowed some files to be sent that included callers who had not consented to randomisation or had already been transferred.
• **File content** – a single change was made at the end of August 2003 to the data received in files from the Contact Centre (removing a data item). The change had not been communicated and this resulted in delays in the file processing.

• **Data transfer errors and delays** – there were teething problems with the transfer process between the Contact Centre and the randomisation team. Errors were found regularly in the first weeks. In the early months a failure in the Contact Centre’s automatic tool identifying clients to be sent for randomisation meant that some callers were not transferred immediately. A manual process was implemented to cover the failure. In later months human error caused some transfer delays.

• **IT changes** – the randomisation software was changed significantly in July 2004 when the Contact Centre IT changes took place (see Section 4.3.3) and this caused some delays to the randomisations. An interim process was implemented for a couple of weeks whilst the software was updated to receive and output files in a new format, and to receive different data items. The delays and interim process were a result of the changes not being communicated far enough in advance of their implementation.

• **Processing files** – similar delays were generated by the randomisation team’s failure to process some files fully, usually when there were different bank holidays at the Contact Centre.

• **Postal delays** – it was believed that the Royal Mail postal strike in October 2003 delayed the delivery of the randomisation notification letters, so for a short period the letters were sent out by Special Delivery and receipt checked online. If the letter had not been received on the expected day, telephone contact was attempted to notify trial entrants of their randomisation result.

Delays were identified by checking whether all callers who had agreed to randomisation had been randomised by matching together the monthly extracts from the Contact Centre and the randomisation team. The majority (97 per cent) of clients were processed from consent at screening to randomisation within the agreed timeframe of two working days. Only three per cent did not have their details sent to the provider within the agreed time. Half of the delays were caused by actions at the Contact Centre (either IT changes, premise changes, or errors). Some delays were caused by errors processing files by the randomisation team, for example when a bank holiday file was omitted accidentally, or incomplete data was received from the Contact Centre leading the randomisation program to declare incorrectly that a file contained no clients.

Most delays and errors did not impact significantly on the volunteers, and most delays were short. When there was a considerable delay (which happened for 14 callers), the trial entrant was contacted by letter to explain, that they should have been randomised but had not been and to invite them to get in touch if they still wanted to participate in the trial21.

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21 None made contact.
Early feedback from providers indicated that when the processing was delayed, the randomisation team was not always notifying the providers. This was frustrating for them because they could not tell whether there had been an error with the transfer or whether the file had not been sent. This was corrected with a reminder that the team should send a warning email to all providers to alert them if they became aware that a file would be delayed.

5.4 Staff understanding of and reactions to randomisation

It was important for the success of the pilot that all Contact Centre and provider staff understood and endorsed random assignment. The Contact Centre advisers did not experience any difficulties understanding and explaining the process to callers which was seen to be a fair method of allocation to the different groups.

Provider staff were also positive about random assignment during the implementation of the pilot. There was a perception that the Intervention Groups would receive some benefit compared to the Control Group which made it easier for the providers to ‘buy-in’ to random allocation. However, after service delivery began some provider staff admitted to having a desire to allocate the most appropriate intervention to their clients, to allow them to receive the treatments they saw as necessary. There were continual ethical dilemmas and unease about the restrictions on advice-giving which were considered to be a result of running the research as a randomised controlled trial (see Section 6.5 for further discussion). Some suggested that the service provided would have been better without the randomisation element although there were no direct criticisms of the randomisation process, and there was a query about whether the evaluation could have been designed without a Control Group so that all of the volunteers would receive some help.

However there was not a sufficiently high level of dissatisfaction for provider staff to feel the need to misallocate clients to different groups, or to continually provide treatments outside the allocated intervention, (there was evidence of some inappropriate treatments being given, but it is unclear whether this resulted from not understanding the treatment restrictions or was undertaken deliberately - see Section 6.4 for more detail). In an isolated case when a client expressed dissatisfaction with their allocated group the provider suggested they reapplied to be put into a different group, which indicated a lack of understanding about how the process worked and how this would affect the evaluation as a whole.

Other staff involved in marketing the pilot identified the benefits of random assignment towards the end of live running commenting that the concept may not have been easy but having three Intervention Groups may have been better than a single group because it portrayed the research as a test looking for the best approach.
5.5 Volunteers’ understanding of and reactions to randomisation

Less than three per cent of callers wanting to join the trial refused to be screened (calls received after 27 June 2004). A reason for refusing was not usually given but there were two exceptions. Three refusals in every 20 were because they could not be guaranteed a specific type of help, and one refusal in every 20 was because the pilot was a research project and/or the interventions were allocated randomly. Both of these reasons suggest that the callers did not agree with the random allocation element of the pilot. However these refusals represented less than one per cent of all callers wanting to join the trial.

One per cent of callers who were eligible, at risk and invited to join decided not to consent to be randomised, which suggests that people did not react negatively to randomisation once they had called the Contact Centre to volunteer. However, we do not have any evidence about whether the randomisation element put off those who did not volunteer in the first place.

A small number of trial entrants allocated to the Control Group (less than three per cent) expressed their dissatisfaction by phoning the information line. Some asked to withdraw from the trial; others were confused and needed clarification on the result of the allocation and what contact they should expect from the research team in the future. Some of the confusion arose from incorrect information given during screening and some from the notification letter.

Despite the small proportion of the Control Group who used the information line, preliminary Outcome Survey data (Stratford et al., 2005), shows that most were quite disappointed at their allocation to this group. Their disappointment may have been quite mild and not severe enough to need to talk to anyone. Alternatively, this could reflect successful recruitment, screening and notification procedures which prepared people adequately and enabled them to accept their disappointment. Or, they may have been very disappointed, but not felt able to phone to discuss it. The lower response rate to the Outcome Survey of this group (66 per cent compared to 79 per cent for the Intervention Groups) may also have reflected their disappointment. The reactions of this group are important to the evaluation, both because they may have experienced real distress and because extreme disappointment might affect their subsequent behaviour compared to someone who had not taken part in the trial. A forthcoming focused study of Control Group members will provide some information about this.

5.6 Reflections

Most Service Provider staff and volunteers accepted the randomised controlled trial methodology. Some of the implications arising from the methodology were not obvious to some of the staff and volunteers, such as not being able to re-enter the trial immediately to be allocated to a different group.
The transfer of client details from the Contact Centre, through the randomisation process to the providers, was timely and generally worked well. The small number of clients whose details were not transferred at the right time was a concern, but not a substantial failure. The randomisation algorithm allocated trial entrants to the four groups as expected. Inappropriate randomisations were sufficiently rare that the random allocation was preserved. However more robust checking procedures should have been implemented at the Contact Centre to prevent some of the delays and transfer of inappropriate cases, and procedures should have been implemented earlier by the randomisation team to prevent some of the processing errors.

It was beneficial to have more than one organisation checking trial entrants’ criteria before they were randomly allocated. This probably resulted in more cases that should not have been sent for randomisation being identified.

The Intervention Group were quite likely to hear the result of the randomisation from their provider before the notification letter reached them. The letter was a useful confirmation and permanent record for trial entrants. Unfortunately, the Control Group were sometimes confused rather than reassured by the content of the notification letter. Whilst our attention to sensitive wording was understandable, clarity is clearly just as important and needed more consideration.

The information line was more useful as a contact for participants who had lost contact details rather than as support for randomisation. Some of the Control Group used the information line for support which indicates that it was probably necessary. Although most did not call, disappointment was common among controls, but more information is needed as to the nature and severity of this reaction.

At the design stage there had been a concern that the delay between screening and the provider making contact would introduce avoidable attrition. The level of attrition experienced was not greater than expected but differed by randomisation group and by area. Attrition was not seen as a significant problem by providers although some trial entrants had returned to work during this period. It was not always clear why trial entrants withdrew after randomisation; it could have been because they returned to work, they decided they did not like the idea of the pilot, they did not like the group they had been allocated to or other reasons. It is difficult to say how much of the attrition experienced could have been avoided if the randomisation process had been integrated with the screening, or the screening and randomisation conducted at providers’ sites.

It would probably have been possible to conduct the randomisation at each provider’s site rather than centrally by a separate organisation. A secure program could have been given to each area. The feasibility for any future trials would need to be weighed against any disadvantages, such as making it difficult to monitor the allocations, the increased risk of contamination of the Control Group and advantages, such as eliminating problems resulting from complex transference of data between organisations. However the centralised approach used here worked well.
6 Service delivery

Procedures were laid down at the design stage of the project to ensure that the way in which the service was delivered to clients met the requirements of the randomised controlled trial. A central component of the Research Adviser role was to monitor service delivery and to raise awareness amongst Service Provider staff where the procedures were not being implemented as laid down.

Given the experimental nature of the trial, those responsible for designing it were doing so without the benefit of any previous model to work to. Much care and thought went into the procedures, although they too were being tried out for the first time. This chapter examines how the individual components of service delivery worked during the live running of the trial, what issues were encountered and how these were handled. It starts with feedback on the initial contact made with clients by Providers (Section 6.1) and the initial meeting (Section 6.2), including how well the consent procedures (Section 6.2.1) and Action Plans (Section 6.3) worked. Sections 6.4 and 6.5 focus on the service provision itself in terms of treatments and advice-giving. Feedback on the providers’ training workshops is given in Section 6.6. The next sections describe how providers dealt with ending clients’ treatment (Section 6.7), and other issues raised such as the database and information recording (Section 6.8) and funding (Section 6.9). Finally, we give our reflections on the issues raised in this chapter in Section 6.10.

6.1 Initial contact

The procedures laid down for making initial contact with clients were designed to ensure that each client was contacted by phone as soon as possible after receiving notification of randomisation, and ideally within 48 hours.

At the initial phone contact, the procedure was for clients to be invited to the Service Provider office for an initial meeting. The intention was for this to happen as quickly as possible. An exception was made initially in the case of the provider which was operating a telephone service: this allowed for the initial contact process to be conducted over the phone and by post.
Preliminary Outcome Survey (OCS) data shows that of those who did not withdraw from the service before the meeting, 29 per cent had it within one week after phoning the Contact Centre and 49 per cent between one and two weeks. Fifteen per cent did not have the meeting until after a gap of three to four weeks, three per cent waited five weeks or longer, and five per cent could not remember (Stratford et al., 2005).

For the most part, Service Providers were implementing the procedures as intended. Given the relatively low numbers entering the trial, this appeared to be a relatively easy task. In a couple of areas, the procedures were not being implemented as prescribed, primarily because of specific staffing arrangements and procedures within the Service Provider organisations. Levels of attrition were markedly higher in these areas. Preliminary OCS data shows that over all areas, 20 per cent of those who left the trial early did so because the provider did not contact them. Moreover, this may be an underestimate, since anecdotal evidence from interviewers was that people were more likely to refuse to take part in the OCS in these areas because they had received no contact or service.

6.2 Initial meeting

The purpose of the initial meeting was to make face-to-face contact, administer the consent procedures and conduct an initial assessment of the client. One provider had built taxi fares for clients into its budget to maximise the numbers coming in to the office for the initial meeting. Where delays occurred between initial contact and initial meeting, it was usually due to previous commitments on the part of clients.

The initial meeting usually included the following stages before a plan of treatment (‘Action Plan’) was drawn up:

- clients watched a short video that described the three-way randomisation, and the written consent procedure;
- they were notified to which of the three groups they had been allocated;
- they were given an explanation of what their intervention might look like;
- they were asked to give written ‘consent’ that they had been given a full explanation of the trial, that they had had a chance to ask questions, that they consented to data being shared across the research team, and that they understood they could withdraw from the trial, or any component of the intervention, at any time.

In most instances this process took place during a face-to-face meeting between the client and a member of the Service Provider staff. Clients were allowed time to consider whether they would like to take part. Those giving written consent could then go straight to the assessment stage. In two areas, the procedures for health intervention clients were different because this was a telephone service; these clients were sent information about the consent procedures by post and asked to
watch the video and sign the consent form at home and then post it back. However, these procedures changed half-way through the trial to become more similar to other areas, due to the higher levels of attrition which seemed to be resulting from this method.

6.2.1 Consent procedures

Clear procedures were laid down to ensure that clients were able to give ‘informed consent’ to take part in the trial. To ensure that these were implemented in an identical way across all providers, the video was made expressly for this purpose with minor modifications to tailor it to the different brand names (WorkCare, HealthyReturn, RouteBack). It contained a clear explanation about the purpose of random assignment as an essential feature of the research. Provider and client feedback on the video was generally positive, with both saying that the explanation given of the trial was clear, logical and comprehensible.

The procedures clearly stated that clients should not be told to which group they had been assigned until they had heard about the randomisation process through the video. Whilst this was generally happening as prescribed, it was apparent from the early Research Adviser visits that some clients were being told which intervention they had been assigned to during the initial telephone contact. The principal reasons for this were either that case managers were not aware of the correct procedure or that clients insisted on knowing before agreeing to come in for an initial visit.

During their early visits to providers, Research Advisers also became aware that provider staff were tending to focus on the service delivery aspect of the pilot, rather than the research aspect, in their discussions with clients during these sessions. Subsequent discussions with staff revealed patchy awareness of the trial objectives and procedures and of the evaluation programme, leading to a perception that service delivery was of greater importance than the research. This was not desirable as it could lead to decisions about treatment that prioritised case managers’ judgement of a client’s needs over the random allocation required by the trial.

Thus it was apparent after the initial visits that staff were not fully aware of all the key messages relating to service delivery procedures and that there was a need to raise their profile. It was for this reason that the Research Advisers, in conjunction with the Department for Work and Pensions (DWP), took the decision to hold a series of training workshops for all Service Provider staff and to issue a handbook specifically designed to assist them in implementing the procedures (see Section 6.6 for more detail).

Once the training workshops had been delivered, it was evident from discussion, observation and examination of case notes at subsequent visits that the consent procedures were being correctly administered and that the Intervention Group was generally not being mentioned until after viewing of the video.
6.3 Action Plans

Service Providers often used the opportunity of the initial meeting to conduct an initial assessment of the client. Once this was completed, staff were required to draw up an Action Plan which was then signed by the client as part of the process of gaining informed consent. The Action Plan served two separate functions. Firstly, it was intended to act as a record of all the actions agreed with clients during their time on the trial. The client was supposed to sign the form for each new treatment agreed. Secondly, it was part of the contractual arrangement with DWP: once it was first drawn up and submitted, it triggered the initial payment to the provider.

All providers made their own client case notes as well as filling in the Action Plan. It was evident from the early site visits that there was considerable variation both in the templates which providers were using for their Action Plans and in the way in which they were using them. DWP subsequently issued a template to standardise the procedure and most providers adopted this. Providers differed in the extent to which they saw the Action Plan as a formal or a working document. Some were using it primarily for contractual purposes. Having sent it to DWP after the initial meeting with the client they used their own separate plans and ongoing case notes to record the client’s progress. Partly, this arose from a concern about client confidentiality if Action Plans had to be submitted to DWP. Other providers were continually updating and reviewing the Action Plan alongside the case notes.

The degree to which providers drew up a detailed Action Plan at the first meeting varied. In some cases, the initial action plan was left deliberately bland, saying no more than ‘refer to specialist consultant’. Two reasons were given for this approach: firstly, that a detailed Action Plan could only be developed once the initial assessment had been conducted and, secondly, that clients might be put off by having to agree to a massive, and potentially daunting, programme.

As part of the informed consent process, providers were required to get the client’s signature every time a new treatment was agreed. However, they all experienced difficulty in doing so, especially when, as was often the case, this was done over the phone and there was no chance to obtain a signature.

The training workshops included a review of the function and purpose of Action Plans, which appeared to communicate the message effectively. For example, one case manager, who had been somewhat dilatory beforehand, became extremely diligent in the way she wrote up her case notes and Action Plans. However, examination of a random sample of case notes and Action Plans revealed some areas where advice and guidance from the Research Advice team was still required, for example:

- Action Plans were not always being revised to record new treatments;
- Action Plans were not always recording when a specified action was subsequently cancelled;
• Expected/actual dates of completion of actions were not always being recorded.
• There were queries about how definite the Action Plan entries needed to be (some entries were being made contingent on the outcome of assessments).
• When a specific action was subsequently implemented, case managers were not always aware that this should trigger a revised Action Plan.

6.4 Treatments and the ‘contamination’ issue

The trial design was intended to provide a clear demarcation between the service offered to clients in the health and workplace groups for evaluation purposes. Accordingly, guidelines were drawn up to prescribe which treatments were, and were not, appropriate for each of these groups in order to avoid ‘contamination’. Examples of contamination are a client in the Health group receiving support for a graduated return-to-work or a workplace client having a fitness programme investigated. The combined group cannot be contaminated by definition because these clients were permitted to receive any health- or workplace-related service.

The Research Advisers received the impression both from observation of treatment delivery and from discussions that provider staff were for the most part clear about what was, and was not appropriate to offer, under each intervention. Most had come to terms with the clearly defined menu of treatments available to them for each group.

Initially, the Research Advisers planned to monitor whether any ‘contamination’ was occurring with regard to the treatments being offered in a particular intervention through an examination of the Action Plans of a random selection of clients. This proved to be insufficient, partly because the plans did not contain enough detail and were only the treatment intentions rather than actual treatments, and partly because a larger sample of clients was needed to identify contaminated clients. Instead, an assessment was made using the information recorded about provider actions and treatments in the Management Information and Evaluation Database. Every client in the database (up to the end of October 2004) was examined to produce a list of all services provided to health and workplace clients.

The database analysis identified a small number of specific examples of clients receiving treatments that were inappropriate, with a higher incidence in the earliest months of live running when the boundaries of the intervention were being learned and established. Due to problems with the treatment information (including missing data) on the database, this may not have identified all the contamination that occurred. However, from the available data, it seemed that in terms of treatments being delivered, the levels of contamination observed were relatively slight. Examples included:

• a client in the health intervention being referred to the in-house Occupational Health Physician rather than to the general practitioner (GP);
• a TENS machine (which relieves pain) being bought for a workplace client;
• mentoring for workplace clients which contained contaminatory advice about dealing with anxiety and panic attacks;
• a letter being written by the in-house Occupational Health Physician for a workplace client requesting various diagnostic procedures and possible treatment.

There was some evidence that contamination was more likely in areas where the case manager worked with clients from more than one Intervention Group and/or where the background and experience of the case manager covered both groups. However, one case manager, working with only one group, was identified as offering clearly inappropriate treatments and actions during discussions and was alerted about it. In this case, it was due to the case manager being unaware of the guidelines relating to contamination.

Preliminary OCS data suggests that contamination in terms of treatment did occur, but at reasonably low levels (Stratford et al., 2005). Ten per cent of all workplace and seven per cent of all health group members were contaminated (according to a self-report measure). Contamination in terms of advice was more common (16 per cent of all workplace and 13 per cent of all health group members) and this is explored in the next section.

6.5 Advice-giving and the ‘contamination’ issue

A much more contentious issue was that of complying with the pilot guidelines about giving advice and guidance. The guidelines laid down in the revised Provider Handbook were quite categorical that any advice and guidance given in the health or workplace interventions should not ‘trespass’ on the other’s territory. Thus they stated that no mention could be made of any aspect of the workplace in the health group. Equally, the case manager could not give any advice relating to the patient’s health condition in the workplace group. If clients asked questions that involved discussing something outside their intervention group, case managers were advised to signpost them to their GP, employer or the Citizens’ Advice Bureau as appropriate.

However, it was apparent both from early discussions with staff and observation of assessment and treatment sessions that these guidelines were not being adhered to. There appeared to be several reasons for this:

• Patchy awareness of the guidelines. For example, one early area of contention was around the area of advice about benefits and debt. At one provider, this information was being delivered to participants across all groups. At another, case managers would ‘signpost’ the appropriate agencies in all groups if the client clearly needed help and advice. A third provider was only giving this advice to clients in the workplace intervention. Referral to DWP led to a ruling that benefits/debt advice was allowed only in the workplace and combined groups.
• Insufficient training of new staff. Briefings had been given to provider staff before live running of the trial. It seemed that new staff joining the pilot since had received relatively little guidance or training on the restrictions around advice-giving. One workplace case manager was quite openly giving advice on anything to clients that might improve their ability to return to work.

• Implementation difficulties. A further difficulty around advice-giving for case managers was the difficulty of interpreting the guidelines and deciding what was appropriate advice in an ‘on the spot’ situation.

• Ethical issues. Staff found themselves facing something of an ethical dilemma when faced with the prospect of withholding advice that could be of benefit to clients. They pointed out that the consent video described them as ‘highly qualified’. In that case, how could they be ignorant of existing services? They also cited the fact that they were bound by their obligations to professional bodies to deliver a ‘duty of care’ to clients. Failure to give advice about existing services would not only go against their own ethos and training but could possibly damage their professional reputation. There was also a perception that they could be deemed culpable in a court of law if they had deliberately withheld information they knew could help a client. Staff therefore experienced a conflict of priorities in which they tended to put their perceived legal and professional obligations before those of the pilot.

• The employment background of case managers. Those with health backgrounds working on the workplace intervention encountered more difficulties reconciling their personal and professional ethical responsibilities with the obligations of the trial.

The Research Advisers felt that the ongoing problems about advice could be resolved in one of two ways. Either the model for advice-giving itself could be amended to allow a more flexible approach or, alternatively, provider staff should receive further training, information and guidance about how to restrict the advice that they offered clients. A particular consideration was the difficulty of monitoring the advice given to clients and the ‘invisible contamination’ that might occur if staff did not adhere to the guidelines. DWP decided that a clear demarcation between the health and workplace groups was essential for the purposes of the evaluation and opted to make some alterations to the existing guidelines for greater clarity. This further reinforced the need for training workshops to communicate the revised guidelines.

It was clear that the workshops subsequently helped to clarify the position regarding advice and signposting and that case managers were generally more aware of what advice was appropriate to each intervention. However, the tension between the constraints of the trial and the practitioner’s professional code of ethics continued. There was some evidence from case notes that case managers’ thinking was still being influenced more by their duty of care to clients than by the trial guidelines and that this was leading to potentially contaminatory situations.
A common view, in part arising from the advice-giving issue, was that the trial design needed to take more account of the factors affecting health professionals and that it was lacking clinical input. It was felt that the design could have incorporated professional ethical obligations more smoothly. Many staff were not involved in the early stages of the design and implementation stages, but would have liked more involvement to determine the procedures that affected them during the trial. They felt that closer involvement may have identified potential ethical dilemmas in advance, as well as enabling staff to become familiar with the procedures as early as possible.

It was also suggested that a three month pilot period of running to clarify definitions, confirm the estimate of numbers recruited and so forth, might have enabled lessons, such as the difficulties surrounding advice-giving, to be learned earlier, and procedures to have been tightened up before the main period of live running.

6.6 Feedback from training workshops/handbook

Provider staff were asked to give their views about the training workshops which were held in late 2003. Overall it was seen as a worthwhile exercise although with some reservations. It was timely to remind all staff that the service was being delivered within the context of a research trial and that that inevitably put constraints on what staff could and could not do. It was valuable to explain the rationale for guidelines, as well as the guidelines themselves, in that it helped staff understand and accept them. Another important function was the explanation of the research evaluation. Not only did this information help staff feel more involved with the trial, it also helped them explain it to clients when any confusion arose. The staff handbook was a useful reference document for ensuring that ‘everyone was singing from the same song sheet’. The perceived downsides of the workshops were the fact that they were carried out relatively late in the project and that reiterating the fundamentals of the trial for the sake of new staff was tedious for those who had been involved from the outset.

However, one provider acknowledged that much of the training for service provision was on-the-job. The main implication of this was that it was difficult for new staff to catch-up to the existing level of experience quickly, so for these staff at least, the workshops were essential.

6.7 Exit strategies

It appeared that providers worked on a case-by-case basis when it came to deciding when to cease providing services (‘exit’ a client). The particular circumstances of the case were reviewed before deciding to suggest that involvement should cease. Providers felt it was important to continue to offer support once clients initially returned to work to ensure that they were able to complete at least the full 13 weeks at work. This was considered especially important in vulnerable cases (for example,
very depressed clients). In some cases, contact was maintained because some longer-term treatment, such as Cognitive Behaviour Therapy (CBT), was still ongoing.

One message, which the workshops had sought to communicate, was that clients were still in the research trial after being discharged by the Service Provider. Any advice given at exit, therefore, had to be appropriate to the client’s intervention. This message had generally been understood and the suggested procedure was being implemented, even though case managers were not always convinced that the Citizens’ Advice Bureau was adequate for dealing with their clients’ problems.

In order to prove a ‘successful outcome’ for clients, providers were obliged to produce evidence that the client had returned to work for a period of 13 consecutive weeks. One aspect of the exit strategy that had proved very difficult was getting clients to provide the evidence that they had returned to work before the pilot ended. Various strategies had been tried, including home visits, but did not improve response rates significantly.

6.8 Database and information recording

Service Providers were required to design and set up their own database for the trial, but many experienced problems doing this. It was widely felt that, with hindsight, it would have been better had there been a standard database for the project that was designed, controlled and pre-tested centrally. This could have helped avoid problems such as those that arose where there was a difference of opinion between DWP and a provider’s IT consultant.

In addition, it would have been easier for providers if more time had been spent at the outset going through the information required in detail and how to record it, for example, how to record telephone calls to employers. This would have helped to avoid the large amount of retrospective data entry which had to be done towards the end of the pilot. Providers also had ongoing difficulties in understanding the data entry requirements, for example:

- being unclear why such detailed contact information was required (for example, recording every phone call made and received);
- finding the data recording repetitive (for example, every treatment session had to be recorded separately rather than recorded as a set of treatments). A facility to copy entries was suggested to improve this;
- they felt that fewer, less detailed and more generic codes would have facilitated more accurate data capture that would have been consistent across all providers;
- they would have preferred an alternative to the ICD10 code frame, which they felt was essentially a diagnostic tool not ideally suited to coding of health conditions. The terms listed on the database did not correspond to conditions that clients presented;
the guidance to data recording (Annex 10 of the data catalogue) needed to be more user-friendly.

The development process – influencing through feedback from iterative reviewing by all interested parties – did not generate sufficient changes at the early stages, partly because providers did not have their ‘users’ in place during the development stage. It became apparent that a fully developed specification had been expected rather than involvement in its development. The development process needed to be recognised, learned and to become part of the culture within all of the organisations involved. Future projects delivered using external contractors should note this and do more to engage contractors as key stakeholders in development so that problems are identified before they impact on performance.

The difficulties with the database are likely to have reduced the quality of the data recorded. Care will need to be taken when the data are interpreted and some compensation may need to be made for items where errors are expected. The difficulties are also likely to have demotivated provider staff.

6.9 Funding

The funding model developed for the pilot was felt to have influenced the service provision. Fees were based on the number of trial entrants, in particular those who gave written consent to receive an intervention, with an extra sum if they successfully returned to work. It was recognised that this acted as an incentive to help clients return to work, but there was a concern that it may not have promoted the client’s best interests if a client did not prioritise returning to work themselves.

A less common view was that the funding model could conflict with the informed written consent procedure. Basing funding on getting written consent and providing treatment benefited the trial because it discouraged high levels of drop out immediately after randomisation. However, this would be detrimental if it was achieved at the expense of not allowing the client sufficient time and information to consider whether to participate. Furthermore the funding model was seen to be unfair because it placed the burden of financial risk firmly with the providers. A further financial issue was raised. Health treatments were seen to be relatively costly and, although providers had reflected this in their costings at the tendering stage, the amounts involved sometimes exceeded the budget available which placed a constraint on the health treatments that could be offered.

It is difficult to be sure about the influence of the funding model on service provision, but it is the case that the burden of financial risk was initially heavily skewed towards the providers. Whilst this was amended during live running with the provision of guaranteed funding which was extended a number of times, the resulting uncertainty permeated the trial and may have caused variation in the treatments available at different points in time.

22 Although it must be noted that the funding model was not followed as intended because of low recruitment.
6.10 Reflections on service delivery

The Job Retention and Rehabilitation Pilot (JRRP) demonstrates the benefits of putting in place procedures for delivering specific aspects of the service in advance. For example, the standard procedures put in place for meeting the Multi-Research Ethics Committee (MREC) requirement for informed consent had worked particularly well. The videos generally worked well both in concept and in implementation and in securing client interest and consent. This was further assisted by the requirement for providers to notify clients about the group to which they had been randomised only after they had watched the video. They were thus well briefed about the trial and the video had been able to dispel any unrealistic expectations that clients may have had about what was on offer.

However, one of the lessons to be learnt from the trial is about the degree to which it is possible to give local autonomy to providers for decisions about delivery and the desirability of maintaining a measure of standardisation and central control. Whilst the standard consent procedures generally worked well, it was where the procedures were being adapted to suit different models of pilot delivery that difficulties occurred. This resulted in remedial action having to be taken to bring the procedures more into line with standard procedures.

The procedures laid down for Action Plans were less prescriptive than those for informed consent. This allowed providers a degree of latitude in how they designed and used them. However, it emerged during the course of the trial that not only were providers using them in different ways from each other but also in ways far removed from the DWP’s original intention in devising them. Action had to be taken retrospectively both in terms of DWP issuing a template and by further guidance in the workshop briefings to achieve a satisfactory measure of standardisation.

It was evident, with hindsight, that providers would have found it easier to work with a centrally designed database, rather than being asked to design their own. It was also evident that providers’ tasks would have been easier if more attention had been given to making the information requirements more “user friendly”, for example by:

- consulting with providers about the coding options to be used;
- minimising the number of changes to the type of information required.

An innovative aspect of the JRRP research design was the total separation of Service Providers from any form of contact or dealings with clients randomly assigned to the Control Group. In previous randomised controlled trials, the Control Groups have tended to use the same agencies that deliver services to conduct client recruitment and initial screening, which significantly increased the risk of ‘contamination’ between the treatment and Control Groups. The JRRP model will undoubtedly pay dividends in making a ‘clean’ and meaningful comparison between the impact of additional interventions on the three treatment groups and that of no additional interventions on the Control Group.
Had the number of pathways been confined to just two (treatment and Control Group), the issue of ‘contamination’ would not have surfaced in JRRP because, as indicated in the above paragraph, Providers would have had no contact with the Control Group\(^\text{23}\). As it was the complexity of the model, which involved providers delivering three different types of intervention, significantly increased the risk of contamination occurring between the health and workplace groups. This ensured that it remained an ongoing issue throughout the lifetime of the trial.

However, the issue of contamination in the existing JRRP model would have been less marked had it been confined solely to the type of treatments delivered. It was not essentially a difficult task for providers to work with clearly delineated treatments in the health and workplace groups so long as they were well briefed. Cases of contamination were identified primarily through examination of client case notes and the database. However, the exact extent of this contamination is difficult to assess until the database entries have been completed. This will be reported in the final report on the trial impact (see Section 1.4).

Whilst the intentions behind the advice guidelines were understandable, it must be asked to what extent they achieved their goals and at what cost. The stated intention of including advice-giving as part of the ‘intervention’ was to ensure as clear a demarcation as possible between the health and workplace groups for evaluation purposes. However, this does not take into account the fact that other sources of advice, such as informal input from friends and from other organisations, may be much more influential in spurring clients to other courses of action than anything inadvertently mentioned by provider staff. Any inappropriate advice-giving that did occur was unlikely to be recorded and is therefore much more difficult for the evaluation team to monitor and detect than with the clear-cut guidelines around treatments. The fact that this cannot be established diminishes the ability of the trial to measure the differential effectiveness of a health versus a workplace focus. Nevertheless, the separation of the treatment options in the model means that it will still be possible to measure the relative effectiveness of a predominantly workplace-focused and health-focused approach.

The cost of attempting to achieve a clear demarcation in terms of advice-giving was considerable. The guidelines provoked substantial antagonism amongst Service Providers on the grounds that it made the intervention ‘unrealistic’ because it would not be sustainable in any roll out of a similar scheme and was unworkable when dealing with clients to whom they had a duty of care. This issue was also a cause of considerable provider alienation from, and dissatisfaction with, the trial management. Even after clarification of the guidelines around advice-giving at the training workshops, Research Advisers were not confident that provider staff would always put this requirement of the trial above their perceived duty of care to the client.

\(^{23}\) Although this two-way design would not prevent advice-giving by the Contact Centre from contaminating the Control Group.
Given the experience of JRRP, our view is that any future versions of this randomised controlled format would be well advised to consider making the issue of advice one that cuts across all interventions while preserving clearly delineated treatments between the interventions.

It was difficult to anticipate the difficulties experienced around advice-giving; if there is a lesson to be learnt from this it is that the first few months of live running should be accepted from the start as part of the development stage, and an understanding that this is the case should be added to contracts. This period would then be used to iron out problems and make changes as appropriate. If the changes are extensive it should be agreed in advance that the data from the first few months could be set aside. This would need agreement from the MREC but would probably be accepted as reasonable. Such a bedding-in period would have allowed any input from the MREC to be fed back into the development cycle at an earlier stage for discussion.

There was a tension between setting the pilot up within a short period of time to maintain momentum, and allowing sufficient time for processes such as the MREC application which was lengthy but could only be done partway through the implementation stage once the trial procedures had been agreed. The recommendation above would allow for time to consider an initial MREC application at an earlier stage without the pressure for it to contain the final details of the working procedures. This would also permit wider consultation with the service provision staff.

The fundamental importance of ensuring all key players are thoroughly briefed before the start of the trial is another key lesson to be learned from the experience of the pilot. Whilst the staff had been trained about the trial procedures such as consent and randomisation there was no central guidance about the interventions. However the issues that arose had not been known before the trial had begun, so it could only have been possible to give guidance at the end of a ‘bedding-in’ period. This type of training is vital firstly for ensuring that those involved at all levels are fully informed about the workings of the pilot and how it should be implemented. A structured approach, as provided by the combination of the workshops and the staff handbook, would have helped to convey and implant key messages had they been delivered earlier in the pilot. The workshops also indicated the importance not only of clearly communicating the guidelines for service delivery but also the rationale for those guidelines. Staff were more likely to understand and accept guidelines if they knew why these were put in place. Secondly, the importance of the briefing as a team building exercise should not be overlooked. Where Service Providers are required to work independently but as part of an overall team, to meet the other players and learn about their role and function greatly increases their sense of ownership of, and commitment to, the project. Thirdly, the workshop provides a forum for provider staff to air and discuss issues of importance to them, which helps with the two way communication essential to the successful working of such an enterprise. Finally, a training period may have helped to identify and reconcile the difficulties with personal and professional ethical responsibilities.
7  Winding down the trial

Providers felt that the final entrants to the trial should have a minimum of 12 weeks in which to receive treatment under the Job Retention and Rehabilitation Pilot (JRRP). It was therefore decided that recruitment to the trial should end in December 2005 and that the trial itself should finish on 31 March 2005. This meant that theoretically participants could continue to receive treatment until the end of March. In practice, providers tended to exit all participants at least a week before that date to allow for an administrative ‘wind down’ period.

This chapter looks at the impact of winding down the trial on specific aspects of service delivery, drawing on material from the final two Research Adviser visits to providers. The penultimate visits, in October and November 2004, focused on what preparations providers had put in place for winding down the pilot and their expectations of how the wind down period would affect the running of the pilot, both in terms of its impact on clients (Section 7.1) and on providers and their staff (Section 7.2).

The final ‘visits’ in March 2005 (some of which were conducted over the telephone rather than face-to-face) focused on providers’ experience of the wind down and the extent to which expectations had, or had not, been realised. The chapter concludes with reflections on what lessons can be learned for winding down any future randomised controlled trial (Section 7.3).

7.1  Impact of the wind down on clients

7.1.1  Recruitment

Providers had had variable expectations about how the approaching end of recruitment would impact on numbers entering the pilot. In the event, numbers had varied across the pilot areas: in some cases, remaining steady or even increasing, in others, tailing off towards the end. Those providers who had agreed with DWP to extend their recruitment periods generally felt that this decision had been justified in terms of the additional numbers that had entered the pilot.
Some concerns had been expressed that there could be problems providing a satisfactory service to very vulnerable or needy clients entering the pilot at the end of the recruitment period. However, at the final visit providers were of the view that, if anything, there were possibly slightly fewer of the more ‘needy’ type of clients entering at this stage although the reason for this was not clear. This did mean, however, that providers experienced fewer problems than anticipated in delivering effective treatments within the timescale of the wind down period.

### 7.1.2 Consent procedures

Providers indicated that they would continue with their consent procedures in exactly the same way as before with the one exception that they would alert clients to the pilot’s end date at the consent interview stage. Failure to do so was seen as going against the stated principle of the pilot to obtain ‘informed consent’. Whilst providers were aware of the need to strike a balance between obtaining informed consent and not putting people off entering the pilot, they felt that alluding to the end of the pilot arose naturally out of the explanation given in the video. They also felt that it was still possible to persuade clients of the advantages to be gained from joining the pilot. The final Research Advice interviews indicated that this policy had continued until recruitment ended and had not had any perceptible impact on participation.

There was little evidence of the wind down having any effect on the way Action Plans were completed except that case managers made sure that clients understood that any new actions undertaken would have to be completed in advance of the end date.

### 7.1.3 Treatments

Providers had given thought as to how to deliver treatment to those entering the trial at the end of the recruitment period. A number of different measures were put in place to ensure that any treatment undertaken could be completed within the time remaining to avoid any detrimental effect on clients. These included:

- making sure that client expectations were realistic by not promising anything that could not be delivered within the timescale;
- looking at ways of speeding up the process (for example, making worksite visits happen more quickly or going to see employers at their premises rather than inviting them into provider offices) or giving treatments more intensively;
- looking for satisfactory alternatives to existing treatments. There was some evidence that the alternatives could have replaced the existing treatments during the trial quite effectively;
- referring clients to other rehabilitation agencies;
- arranging for subcontractor help in advance so that clients were not left without support.
Providers had anticipated that some chronic physical problems and situations where patients were waiting for (or recuperating after) surgery might present problems and in a few cases certain types of medical treatment, such as lengthy physiotherapy or a specific operation, had to be dropped because of the timescale. Providers had either looked at alternative ways of helping the client themselves or had referred them to other agencies, including the National Health Service (NHS), for treatment. The length of time involved in Welfare Rights appeals had also precluded this form of intervention and had been replaced by a referral to the Citizens Advice Bureau.

One area where providers’ concerns were not fully realised was in the area of mental health. It had been anticipated that some mental health conditions would present a challenge to deal with given the limited timescale. However, there were few reports of any issues around this although it was not clear whether this was simply due to good fortune in the types of client entering the trial at that stage.

A perceived benefit of the wind down period was the amount of time that case managers had been able to devote to existing, as opposed to new, clients. It was widely felt that the relationship with the case manager was the most significant boost that clients received from the pilot. The boost consisted in the first instance in the ‘listening ear’ that the case manager was able to supply. Clients referred to the ‘isolation’ of being in a long-term sick situation. Access to the case manager removed the sense of isolation and enabled them to share the issues and problems, emotional as well as practical, that they were experiencing. This in turn helped the client’s morale. In addition, the case manager was able to talk through issues from an informed perspective, identifying possible ways of resolving the issues raised. Thus the client was simultaneously benefiting from professional advice and support. It was likely that existing clients benefited significantly from the higher level of input that case managers were able to provide towards the end.

At the end of the project, providers generally felt that the measures taken to deliver treatments had worked well. Generally they felt that careful planning had enabled them to deliver and complete treatments effectively.

### 7.1.4 Exit strategies

The focus of provider staff during the wind down period changed from delivering treatments towards achieving a satisfactory exit strategy for clients. An area of concern was the fact that staff were unable to provide return to work support to those returning to work towards the closing date. Previously they had been able to offer some continued treatments during this time and, most crucially, support through telephone contact. The latter was felt to be especially important to more vulnerable clients such as those with mental health conditions. Providers’ concerns were that the lack of return to work support would diminish the boost that they were able to offer which in turn would reduce the numbers completing the 13 week period required for a successful outcome. In some cases, providers managed to refer clients to alternative agencies for this type of support.
7.2 Impact of wind down on Service Providers and provider staff

7.2.1 Marketing
The wind down period provided something of a challenge for marketing teams. On the one hand, it was important to keep the marketing initiative going in the short term to make sure that numbers did not taper off before the end of recruitment. On the other, there was a need to alert key players involved in marketing to the pilot’s imminent conclusion to ensure that marketing activity diminished in the medium term. There were inherent risks that activities designed to achieve the latter might adversely affect those designed to achieve the former.

Strategies for maintaining recruitment in the short term included sending out large mail shots to potential clients or doing a radio campaign as ‘one last push’. Some providers kept up the pressure on selected general practitioners (GPs) with a proven track record or sent a ‘last chance’ letter to key players. One felt that the marketing methods put in place were designed to be self-sustaining so there was no need for any last minute push.

Providers’ strategies for ensuring the wind down of the marketing happened in a timely and effective fashion involved discontinuing efforts to visit and recruit certain stakeholders (such as employers). It also involved sending out letters to all key stakeholders (GP practices, employer organisations, trades unions) to thank them for their participation, asking them to cease referrals and to dispose of marketing materials after a certain date.

Providers sometimes took personal responsibility for ensuring that any promotional materials were destroyed, for example by carrying out spot checks at selected GP and employer premises. One marketing team, aware of the difficulty of getting this kind of action undertaken in secondary care, visited local hospitals themselves to take down posters and other promotional material. It was unlikely, in the view of one provider, that word about the ending of the pilot would reach all organisations involved in marketing so some volunteers would still come forward even after recruitment had stopped (which was indeed the case).

7.2.2 Staffing levels
The implications of the wind down for staff differed significantly between those organisations which had been delivering the pilot alongside their other core activities and those organisations which had been set up specifically to deliver JRRP and which were due to be wound up on completion of the pilot. Staff working for the former were gradually devoting more and more of their time to working on core activities until they were on them full-time again by 31 March 2005. It had therefore been easy to regulate staffing levels in this way and there were unlikely to be staff leaving as a result of the pilot coming to an end.
There were a range of implications for organisations set up specifically to deliver JRRP. Staff had been taken on for the duration of the pilot and now that the end was in sight, they were naturally looking for other jobs. Providers had mostly sounded out their staff to assess the level of existing staff that they could count on until the end of the pilot. Where there was any actual, or likely, shortfall, providers sought to cover this by seeing how existing staff could cover any gaps until 31 March and, if necessary, making revisions to their contract. For example, one provider had successfully catered for the staff shortfall by using unqualified staff to take routine tasks, such as walking with a client, thereby freeing up qualified staff to deliver more specialised tasks. Providers also looked at how their external contractors could be deployed to make up any shortfall, although this did not prove necessary in the end. Indeed lack of demand had sometimes led to cuts in the use of external contractor services.

Generally, providers felt that they had managed to regulate staffing levels satisfactorily during the wind down period. There had been some natural wastage from staff leaving for other jobs but redeployment of existing staff and extending contracts of key staff had meant that they had managed to provide adequate staff coverage.

7.2.3 Staff workloads

Providers had generally anticipated that staff workloads would inevitably change once recruitment ended, firstly because of the absence of new clients and secondly, because the focus would be on making sure the client files and database were in order before the project ended. There was also the unknown factor in the effect that staff leaving would have on the workloads of staff remaining.

In the event, the predictions turned out to be fairly accurate. Case managers found the bulk of their casework related to dealing with Action Plans and planning exit strategies for existing clients. The shift towards administrative work related to tidying up the database and case files also turned out to be accurate although sometimes the amount of work involved turned out to be greater than anticipated. There were a number of reasons for this:

- having to contact clients to find out their current status;
- chasing up reports from consultants;
- checking client files against the database;
- recoding of data to meet changing requirements.

For the most part, staff workloads had remained manageable with one or two exceptions, such as when a member of staff had left unexpectedly and a colleague had been required to fill the gap. To a certain extent this had been compensated for by a decrease in client caseloads.
7.2.4 Financial implications

Financial implications of the wind down varied, with some providers making active provision for the end and others not doing so. Provider organisations specifically set up to deliver JRRP had been aware that their sources of income were due to come to an end at different stages during the wind down period. Recruitment funding was due to end once recruitment stopped and they would be unable to obtain the outcome related funding for those clients who had not completed 13 weeks return-to-work before 31 March 2005. With one exception, this had concentrated their attention on making provision for the wind down period. For example, they had opened a contingency fund to cover the staff and other associated costs likely to be incurred during this period. Where this had happened, and especially where the money set aside for staff redeployment had not been required, the finances had proved to be amply sufficient. One provider in this category had failed to implement proper measures to cover the wind down period, which was largely due to internal problems around financial management.

Provider organisations delivering JRRP alongside their core activities had tended to make less active provision to cover wind down. Income from the pilot was not essential for covering the period in the same way it was for organisations devoted exclusively to JRRP. The ending of the pilot had adverse financial implications because of the loss of the recruitment and outcome funding.

Providers had originally elected to end recruitment to the pilot at different dates, some considerably earlier than others. This had financial implications in that recruitment funding would be ending at this stage. To boost the numbers entering the pilot, a couple of providers had agreed with the Department for Work and Pensions (DWP) to extend their recruitment period in exchange for guaranteed funding. Financially, these providers considered that they had benefited significantly by getting one month’s extra funding and having one less month in which to spend it.

7.2.5 Database and records

Providers had made provision to close down cases at least a week earlier than the end of the pilot so that the data could all be collated and checked before being handed over. Dealing with the database and administrative records at the end of the project proved to be quite challenging in a number of respects:

- Firstly, there were conflicting messages about what was required. For example, it was not entirely clear whether it was necessary to wipe out all traces of the data, nor who would do this (an external agency or the providers themselves).

- The actual requirement to wipe the data caused some concern for a provider using the database from its core business to record JRRP data. As it was part of a wider IT system, there was a perceived need to have a financial audit trail and to have access to records in case of a client threatening to sue. This concern did not appear to be shared by other providers.
• A particular problem identified was how to fill in the database where the provider had insufficient details from the client about their outcome. There was some feeling that DWP should have provided more guidance around this.

• The intention had always been that data should be handed over to DWP as the data controller at the end of the trial. Confidentiality was promised to clients on the basis that the information would be shared with the evaluators. However, providers had not fully recognised the implications of this which gave rise to concerns about protecting client confidentiality towards the end of the trial.

Provider organisations differed in the extent to which they managed to maintain records during the live running of the trial. In some cases, a temporary shortage of case managers led to shortcomings in maintaining client files and the electronic database. This resulted in case managers having to undertake a lengthy exercise in the last days of the trial trying to make sure that the two sets of records corresponded.

7.3 Reflections on the wind down

Overall, a key lesson to be learned from the wind-down period is the importance of forward planning about how to deal with specific aspects of the process. Providers who had developed a specific wind down strategy felt that it had paid dividends, particularly in the key areas of financial planning, marketing, staffing requirements, treatment provision, discharge/exit procedures and administrative records. The DWP guidance on various aspects of the wind down process appears to have been helpful as a model and it would be useful to have something similar to work to in any future trial.

For providers, there was a balance to be struck between the need to maintain recruitment as long as possible and the need to provide as full a service as possible to late entrants. A full service included offering a range of treatment options and also return to work support which providers considered an important element in achieving a successful outcome for people who have been out of the workplace for a considerable period of time and may be lacking in confidence. Despite the financial advantages to providers from extending their recruitment periods, there were some concerns that shortening the wind down period might have an adverse effect on the treatments and support offered, resulting in less sustainable outcomes.

The experience of JRRP seems to confirm the viability of sticking to the same consent/assessment procedures as for the rest of the trial and for completing Action Plans in the same way. One key difference that emerged is the importance of preparing clients psychologically for the ending of the pilot by making them aware of the timescale involved when administering these procedures.

It is clear from this experience that having to work to a tighter time frame during the wind-down period has the potential for concentrating the minds of both case manager and client on how best to deliver and complete effective treatment. There
was some evidence that it encouraged creative thinking about the types of treatments used and the timeframe in which they were delivered.

The benefits of thinking through the impact of the wind down on staffing levels and workloads was apparent in the accounts of Service Providers. It enabled them to look at a range of contingency options for coping with staffing levels, including extending existing contracts, revising working practices and the use of external contractors to cope with any shortfall. Nevertheless, there was a risk of a decrease in the quality of client rapport where staff were obliged to take on an increased workload at a late stage.

The impact of a change in the type of workload was an area which merits greater consideration. Where staff are having to adapt from a client centred to an administrative role or where they are having to work with a different type of client (in this case with clients from different groups) there are implications for stress levels and morale which need to be considered. There is a case to be made for forewarning staff about these potential implications of the wind down and preparing them for it.

This trial has illustrated the importance of adequate forward planning with regard to systems and record keeping. The IT used for the trial was the responsibility of each provider and it is clear that it would have been beneficial if they had developed and tested it before live running of the trial. In addition, greater accuracy and efficiency on the part of Service Providers during the lifetime of the pilot could have saved a lot of staff input on retrospective checking and amending of client files and the database.

However, responsibility for determining what data was required and how the data would be used lay with management. Service Providers felt they would have benefited from a more thought-through and strategic approach on the part of management to the data required at the end of the project before the trial started. This would have helped avoid the considerable extra work for staff that arose from requests for new data and from changes to existing data during the course of the trial.

An area of considerable difficulty for providers was obtaining data about their current situation from clients who had left the pilot. Whilst it is not clear what more could be done to prevent this, it is worth thinking through how best to make clients aware of the importance of complying with this request whilst they are still receiving treatment.
8 Management, communication and evaluation

This chapter focuses on the issues of management structure (Section 8.1) and communication (Section 8.2) as seen from the perspective of Service Providers. In particular, it looks at how these worked in practice and their implications for working relationships between the different players and the efficient relaying of information between them. The chapter also considers whether any gaps in information provision were identified (Section 8.3) and the role of the evaluation as seen from the perspective of providers (Section 8.4). It is important to stress that the views expressed in this chapter only reflect those of Service Providers as stated in meetings with Research Advisers. It is not able to represent the counterbalancing views of staff involved in managing the pilot within the Department for Work and Pensions (DWP) and is therefore inevitably one-sided.

The chapter concludes with reflections on the part of the research team on lessons that could be learned for any future randomised controlled trial (Section 8.5).

8.1 Project management structure

The trial was managed by a project team put together by DWP on behalf of itself and the Department of Health (DH). The project management team was split into two discrete parts with separate areas of responsibility. Disability and Work Division\(^{24}\) (DWD), located in London, had responsibility for overseeing the evaluation, and the contract management group located within Jobcentre Plus in Sheffield, had responsibility for administering the service delivery side of the trial.

\(^{24}\) The evaluation team was situated within the Information and Analysis Division (IAD) at the time of the trial but has now moved to the DWD.
Whilst Service Providers understood that DWP was undertaking to run the trial within the structures and regulations of a government department, they felt that having a ‘split’ management structure was not the most satisfactory model for running the project because:

- Having split locations meant there was a lack of any clear geographical focus to the management team. Ideally they would have preferred to deal with a team at one location. This would have avoided having to make arbitrary decisions when it was not clear to which part of the DWP team a particular query or issue should be addressed.

- Having the two parts of the team responsible for different aspects of the pilot meant that they tended to be working to different agendas and that this sometimes led to friction.

Providers were unclear as to who was running the trial. They would have felt more comfortable with a management structure in which a clearly identified project manager had the authority to liaise between the different players and have the final say over decisions. As it was, it was not clear how decisions were made and by whom. There was a widespread perception that the two parts of the management team often had difficulty agreeing a clear course of action. In the absence of any other explanation being provided, this was held to be responsible for the length of time it took for decisions to be taken and implemented, for example the length of time it took for the new contact centre script, the revised marketing and the Med3s to be brought on stream. These delays were seen to have had an adverse effect on the pilot.

Frequent changes of personnel occurred within both management teams during the course of the trial. The fact that these changes were often not publicised to provider staff meant that they tended to be confused about who was actually involved in managing the project.

Providers also took the view that, had there been someone with overall responsibility for running the pilot, it would have been easier to provide a clear management style and focus. This might have helped dispel the impression amongst providers that the management style was ‘top down‘ rather than collegiate. In particular, it might have achieved this by:

- Having a more visible management presence at Service Provider premises. Providers felt that management would have demonstrated a greater sense of commitment to the project if those responsible for devising the policy had visited more often to see how it was working in practice. The possibility of discussing issues face-to-face would also have helped to bridge any perception of ‘them and us’ between those devising and those delivering the policy. One case manager said that she had been with the project since it started but that she was still ‘anonymous’ as far as the management was concerned and that this did not help to capitalise on the very real sense of commitment which staff felt.
Those within DWP responsible for determining procedures making a more active attempt to consult with Service Providers about specific features of the project. This would have helped to counter their prevailing perception that management made decisions without any reference to the culture and working practices of those involved in delivering rehabilitation and healthcare services.

8.2 Communication

A key task for the project management team was that of managing communication between a number of different players. The DWP management set up two initiatives to act as communication channels. Firstly, there were a series of Service Provider workshops throughout the trial which were designed to act as a forum for the exchange of ideas between Service Providers and between providers and management. Secondly, the National Centre for Social Research (NatCen) Research Advice team was formed to monitor and relay trial procedures to Service Providers and act as an intermediary between providers and DWP. Providers broadly welcomed both these initiatives and considered them helpful vehicles for promoting communication. However, what was felt to be lacking was a more strategic approach towards actively managing the overall style, content and delivery of communication within the project on a day-to-day basis.

It was generally felt that day-to-day communication between management and providers could have been improved with more clearly defined channels of communication. This could have avoided cases where information and guidance was coming from more than one source leading to inconsistency in the messages being communicated. An instance of this was the ‘signposting of advice’ issue (see Section 6.5) where providers felt that they were receiving contradictory messages from NatCen and DWD.

Clearly defined channels could also have speeded up responses to a message or suggestion. It was not always clear to whom a particular issue should be referred (to DWD, NatCen or contract management group?). Issues were often bandied to and fro between the different parties which resulted in lengthy debates and deliberations. This could have adverse consequences for the pilot. For example, the length of time it took to get postcodes extended and the delays in receiving the new marketing leaflets, both had a potentially adverse effect on recruitment. With more clearly defined channels of communication, providers might have been aware of extenuating factors such as the length of time required to get changes approved by Multi-Research Ethics Committee (MREC).

Ensuring that lines of communication were kept as short as possible was also seen to be important. Otherwise key information and messages could be lost. One example of this arose where responsibility for communicating information about the training workshops to Service Providers was devolved from NatCen to contract management group with the result that key messages about organisation were omitted. Time and energy then had to be taken on remedial action which could have been avoided.
A more actively managed and strategic approach to communication could also promote:

- Consistency of messages between the different parties. Providers felt that messages about the types of actions that they should be undertaking as part of service delivery tended to be somewhat inconsistent. There were also comments about the goalposts being moved, most notably with regard to the database but also with regard to the handling of Action Plans and client outcomes.

- Proactive provision of information. Providers felt that it would have helped had the training workshops and handbook been provided at the outset of the project rather than once it was up and running. This would have helped to give a higher profile initially to key messages about the trial, for example the importance of the evaluation or the rationale for the signposting advice, thereby avoiding some of the early confusion.

The contract management group met providers on a regular basis to discuss contractual issues. However, it was felt that more face-to-face contact between members of the management team and Service Providers would have helped foster a more ‘collaborative’ style of communication. It was easier to resolve issues during face to face discussion rather than communicating via email. Examples of where this would have proved beneficial included:

- issues raised about service delivery, for example the design and function of Action Plans;

- cases where a provider deemed it ‘unsafe’ for a client to take part in the evaluation;

- giving a clear rationale for why things should be done as stipulated: for example an explanation about why the fields on the database were there.

Issues around communication were not confined to contact between Service Providers and the management and evaluation teams. They also occurred internally within provider organisations. It was clear from discussions with provider staff that there were instances of important information relating to the project not being communicated to internal staff. For example, staff taken on at a later stage were not always receiving key messages about the advice guidelines. Similar problems were also identified between Service Providers and their subcontractors.

8.3 Information gaps

Providers identified some areas where they would have valued more information. Whilst there was some understanding about the importance of maintaining separation between the Contact Centre and providers to avoid any contamination of the Control Group, the lack of information about the remit and workings of the Contact Centre could be interpreted as an indication that providers were being treated as junior partners in the project. Assigning a Contact Centre adviser to each provider to act as information broker for new clients later on in the project went
some way towards redressing this situation (but also had its disadvantages – see Section 4.3.2).

Opinions differed as to whether provider staff would have welcomed information about their performance in relation to other providers. Perceived advantages included making staff feel more involved with the wider project and less as if they working in a vacuum. Feedback could have been used to encourage and motivate staff. It would also have helped morale for case managers to have had the opportunity to share ideas and problems with their counterparts in other provider organisations. Perceived disadvantages would have included concerns about business confidentiality and about such information proving divisive.

8.4 The evaluation

Providers generally felt that it would have been helpful if they had been better informed about the structure and timetable of the various components of the evaluation. It would have helped providers feel more integrated into the mainstream of the research trial. Indeed it would also have helped reinforce the message that their work was as much about participation in research as about delivering a service. This was a message that staff could easily lose sight of in their day-to-day work. The information given about the evaluation at the training workshops was appreciated and acted as a useful reminder, but would have been more useful if given earlier on in the trial. Being better informed would have been helpful in several ways:

- It would have helped them understand what interviews clients were doing. For example, it would have helped them to realise that when a client talked about participating in a telephone interview, this was probably a reference to the panel study and unlikely to be either of the surveys.

- It would have helped them in sorting out cases of client confusion. Clients occasionally had difficulty distinguishing between the delivery and evaluation components of the trial even though they received an advance letter on NatCen letterhead and were shown an ID card by survey interviewers. Those who had recently taken part in a survey interview sometimes could not understand why provider staff were ringing them up and asking them the same sorts of questions. Providers would like to have known when survey interviews were being conducted during the trial so that they could immediately sort out this type of confusion (although there would be practical and ethical difficulties with providing this information).

- It would have helped their own understanding of what the evaluation could achieve. Providers expressed reservations about how the impact of the trial could be evaluated given the different models being used to deliver the same interventions in the different areas. There was also some dissatisfaction that the different areas could not be evaluated separately so that providers could see how their model performed in relation to those in other areas. However, DWP has agreed to provide feedback on how each area performed in relation to the overall performance for each intervention.
It would have helped avoid the perception that staff views and professional judgement were being overlooked. This could occur where a provider had recommended that a particular client should not be approached for the survey, either for reasons of interviewer safety or because they felt that the client would be harmed by the interview, and the suggestion was rejected.

It could have helped counter scepticism among providers about whether the cost-benefit analysis, which was regarded as a burdensome task for provider staff, would produce anything useful.

Provider staff also relayed feedback from clients about the evaluation. For the most part clients had commented favourably on taking part in the evaluation, some finding the Outcome Survey (OCS) interview useful as a validation of what they had to say about the services they had received. However, a couple of case managers had had feedback from a few clients that they had found the interview intrusive and lengthy.

Other clients were not sure how the data would be used and whether their employer, general practitioners (GP) or the benefit office would have access to it. Being told that the survey ‘would not affect their benefit entitlement’ did not reassure some clients as they felt that this statement would be true even if their data were used to identify false claims. Another comment reported was that clients had not known how to check the identity or credentials of the interviewer.

As already mentioned, the Control Group were less likely to respond to the OCS, presumably due to disappointment and feeling that as they had not received any help, they were not obliged to help the trial.

8.5 Reflections on management, communication and evaluation

One of the key themes emerging from the experience of running the Job Retention and Rehabilitation Pilot (JRRP) is the crucial importance of establishing and maintaining good working relationships between the different players involved. Where this occurs, it is likely to engender a strong sense of commitment to the project and high morale leading to enhanced performance. It is evident that these types of working relationships are likely to be fostered where there is a clear, accountable management structure combined with effective mechanisms for ensuring that communication between key players flows quickly and effectively.

It is clear that the pilot highlighted a number of areas around both the management structure and the handling of communication that could be improved in any future randomised controlled trial.

The importance of an identifiable and accessible management structure is one of the key lessons to be learnt. Whilst government departments have their own established methods and ways of working, it is imperative to find ways of adapting them when
undertaking initiatives of this sort. The running of the pilot would undoubtedly have been more effective if a dedicated project team, combining both the research and implementation teams, had been set up in one geographical location. This would have had a number of positive advantages, as it would have:

- been easier to establish a sense of common purpose;
- helped create better dialogue between the two parts of the team because they would have been able to talk to each other and discuss issues more easily. This may also have speeded up decision-making;
- helped avoid a ‘them and us’ mentality which was a potential risk with such a large number of players;
- provided a clear focal point for other players involved in the pilot.

Despite it being the policy within government departments to move staff on at regular periods, there would have been considerable advantages to ensuring maximum continuity of staff within the dedicated JRRP management team. The advantages of maintaining comparative continuity of personnel would have been the opportunity for building relationships with the other players and in giving a message of commitment to the project. Where personnel changes did occur, it would have been helpful for providers to have been notified.

It was evident from provider feedback that a clearly defined management hierarchy for the JRRP trial would have helped so that all players would have been fully aware about who was running the trial, who had responsibility for taking decisions and who was ultimately accountable for decisions taken.

Among the potential advantages of having a clearly defined person or persons heading up the management team would be:

- providing a clear management steer and tone;
- co-ordinating the disparate activities of the constituent parts of the team;
- arbitrating between disagreements about policy or actions between the different players within the management team;
- speeding up decision-making;
- dealing at a senior level with different departments and policy customers.

The trial also highlights the importance of ‘active management’ of communication when running a trial of this scale involving a number of different players. It needs to be noted here that communication issues were not solely confined to those between DWP management and Service Providers but also related to communication between, for example, DWD and contract management group, NatCen and the providers, and NatCen and DWP, and within each organisation.
Active communication could be promoted in a number of different ways for any future randomised controlled trial. Firstly, it could be fostered by seeking consultation with all parties involved – by a ‘partnership’ approach. This could start at an early stage by ensuring that those involved in delivering the project had an input into it at the design stage. It would continue by ensuring a channel of ongoing two-way communication throughout the project. It could be further developed by members of the management team making personal visits to provider premises to find out how things were working. This would help to give all players a sense of ownership and take away the impression of a ‘top down’ approach to communication and management. Some of the tensions occurring in the provider workshops stemmed from providers feeling that their views were not listened to or considered important by management.

Secondly, it could be promoted by a ‘proactive dissemination’ of information. Elements that would assist here include:

• arranging for thorough briefings and documents at an early stage so that those involved in delivery feel fully informed and have sufficient guidance from the outset;

• providing the rationale for any guidance given as well as the guidance itself.

Thirdly, it could be reinforced by speedy responses to issues raised, and by having a dedicated contact within the management team to act as broker for queries and have responsibility for ensuring that responses are delivered swiftly. For JRRP, providers were asked to channel all enquiries through their contract manager and an issues log was set up to try to ensure problems were resolved quickly.

Another factor that merits consideration is how communication should be conducted. One finding from the research trial is the importance of maintaining short lines of communication and clearly defined communication channels. The problem of conflicting messages tended to arise where messages were being relayed in different directions by different people.

The importance of communication for fostering a partnership approach leading to higher morale, staff commitment and effective working is also exemplified by the way in which the issue of the Contact Centre was handled. It was important to actively communicate the reason for keeping a clear separation between providers and the Contact Centre but also inform provider staff about how clients were screened, recruited and randomised. Similar advantages were also to be gained from more active communication about the evaluation.

A key strength of the pilot was its ability to take retrospective action where this was deemed to be necessary. It applied to the marketing, the Contact Centre script, and communication with regard to increased information about the Contact Centre and the evaluation. The timing of the training workshops was not optimum but holding them led to provider staff feeling better informed.
Finally, consideration needs to be given to the value of the two initiatives set up to further communication within the trial. The provider workshops were a potentially valuable forum for issues of mutual interest and relevance to provider organisations. However, the ongoing problems of communication tended to hamper them from reaching their full potential: on occasions they could become a forum for airing grievances rather than putting forward positive ideas and suggestions.

The Research Advice role turned out to be as flexible as had been envisaged. It proved invaluable for:

- monitoring the statistical progress of the trial and checking the information collated;
- for monitoring the workings of the Contact Centre and the Service Providers;
- for carrying out ad hoc projects on specific features of the trial as required.

In addition, it was able to identify areas where remedial action could improve the quality of the trial: for example, revisions to the marketing and the contact centre script and the setting up of provider workshops.

One area in which the Research Advice role turned out to be possibly less effective than envisaged was in providing speedy and consistent responses to provider queries. With hindsight, it could be argued that acting as the broker between providers and management may have lengthened the lines of communication and contributed to a more distant relationship between the two parties. However, it could equally be argued that a centralised and clearly defined management structure within DWP would have enabled decisions to be taken more easily and speedily, thereby helping to make the Research Advice role more effective.
9 Conclusions and recommendations

This chapter brings together the findings of previous chapters and considers their implications for this and for future trials. Recommendations are included throughout with future randomised controlled trials in mind.

Despite problems with recruitment (covered in Section 9.1), most of the key aspects of the trial’s design worked as intended. Screening and randomisation ran smoothly and fulfilled their aims (Section 9.2). Consent procedures were adhered to and overall attrition levels were no higher than expected. Interventions were delivered without very high levels of contamination in terms of actual treatments, although advice-giving was a problematic area (Section 9.3). Management and communication were other problematic areas and recommendations regarding this are given in Section 9.4. Problems were also experienced with the management information system (Section 9.5).

9.1 Marketing

As is often the case among trials, recruitment was a difficult process and numbers volunteering fell far short of providers’ initial expectations. Providers identified a number of reasons for this. They felt that they needed better information in producing their initial predictions. Also, marketing should have started earlier with more time to raise awareness. The trial design and ethical considerations placed restrictions on marketing that providers felt were unhelpful. For example, the reason that providers were not allowed to recruit potential volunteers themselves was to avoid any contamination of the Control Group. However, providers themselves felt that they have could have been persuasive about the merits of participating in the trial, had they been allowed to do this, and would therefore have recruited greater numbers. The fact that the content of the marketing was prescribed and that it was obliged to mention certain points about the trial, was also considered a barrier in that some of these were felt to be counter-productive to recruitment. However, many of the restrictions were a condition of receiving ethical approval for the study.
For any future trial, a number of factors related to marketing and recruitment should be taken into account:

- More resources need to be invested in obtaining realistic estimates of the size, location and characteristics of the target population.
- Consideration should be given to starting the marketing process earlier, during the implementation stage.
- The possible trade-off between preventing contamination of the Control Group (by preventing providers having contact with volunteers before randomisation) and effective recruitment should be considered.
- Where ethical considerations allow it, there should be careful scrutiny of marketing messages for their appropriateness, and consultation with providers about them.

The marketing techniques employed undoubtedly had an effect on the composition of the sample recruited. Providers targeted employers that would give the greatest returns, which included an over-representation of large and public-sector employers. Recruiting via general practitioners (GPs) may have produced a more representative sample, but even then, care has to be taken that GPs cannot be selective about who they recruit. Some providers would have liked GPs to have been able to refer volunteers directly onto the trial.

- Future trials need to consider the effect of sources of recruitment on the representativeness of the sample recruited. Using GPs as the major source of sample may be preferable from this point of view.

9.2 Screening and randomisation

Almost all volunteers were willing to be screened and gave positive feedback on this process. The screening tool was successful in reducing deadweight to below the target of 50 per cent. The relatively small proportion screened out suggests that in this case, self-selection would probably have been sufficient, but this could not have been guaranteed, so the screening was still a worthwhile component of the trial.

Almost all of those who were screened-in were willing to be randomised and most understood that there was a chance that they might not get any help. The randomisation process worked smoothly and successfully randomised volunteers equally to the four groups with very few errors. Most players accepted the randomisation as a key part of the trial.

The randomisation process worked well because the algorithm and systems were subject to extensive testing before go-live. The process was rigorously monitored after go-live and additional checks introduced to solve any emerging problems.

- This testing and monitoring of such a key element of the trial should be included in any future randomised controlled trial.
The centralised screening and randomisation was successful in preventing any significant contamination of the Control Group, and also in preventing anyone from influencing the randomisation outcomes. The alternative (having screening and randomisation devolved to the individual Service Providers) would have entailed a much greater risk of Control Group contamination and also of ‘gaming’, that is the possibility that providers might work out the block size from the sequence of past randomisation results and anticipate where in the flow to put volunteers whom they felt especially needed a particular intervention to increase the likelihood of getting it. This was much less likely with the centralised design as the agency doing the sequencing of submissions for random assignment (the Contact Centre) had little contact with individual applicants to form a sense of any special needs. The Contact Centre advisers also lacked the specialist knowledge of the Service Providers so there was less potential for them to be able to contaminate the Control Group.

- For these reasons we recommend that future randomised controlled trials also take this centralised approach to screening and randomisation.

As with any questionnaire, it is important that the questions in the screening tool are clear and easily-understood by volunteers and that the explanations of the trial are clear. Most volunteers gave positive feedback about these, but a significant minority did not. Listening to recordings of interviews in the early stages of the project confirmed that some of the questions and explanations were unclear.

It is also important that the screening tool is administered in a consistent way, and that no attempt is made to influence volunteers’ answers.

- We recommend that the screening tool in future trials is subject to full testing before go-live, including a pilot with a group of volunteers.

- Contact Centre advisers should receive detailed training before go-live about how to ask the questions consistently and without influencing people.

It must be recognised that it is possible that the screening and randomisation process had unintended effects on who volunteered for the trial. Although these stages did not seem off-putting for those who phoned to volunteer, we have no way of knowing whether there was a group of people who were put off volunteering altogether by the fact that they would have to be screened and/or randomised. However, we feel that this is unlikely given that the marketing materials did not go into much detail about these aspects.

The fact that the screening took place on the phone may have also influenced the characteristics of those who volunteered. Those who had difficulty using the phone (perhaps because of their health condition or disability) may have been put off volunteering. Providers suggested that this may have, in particular, led to an under-representation of those with mental health problems in the trial.
9.3 Service provision

The consent procedures were administered correctly in most cases and thus we can be confident that Intervention Group participants gave their informed consent to take part. The video was an especially useful tool in explaining the trial and most clients and Service Providers gave positive feedback on it. The consent interview was best conducted face-to-face rather than by phone/post, as the latter method led to greater attrition and could not guarantee that clients watched the video. Attrition overall was no higher than expected, although it varied a great deal from one area to another.

The one part of the consent process which did not work well was the Action Plan. This was due, at least in part, to a lack of a clearly defined concept as to the function and purpose of the Action Plan. The first Action Plan was generally completed as required. However, subsequent revisions to the plan were often not completed. A particular difficulty was encountered in getting client signatures to consent to revisions. Although the purpose of this was to gain consent for the actual treatments offered, not all provider staff accepted the necessity of this.

- The consent procedures could be repeated with few modifications for a future trial. However, they should always be administered face-to-face.

- More thought would need to be given to the purpose of Action Plans or their equivalent, especially whether it is necessary to gain a signature for every revision, which providers found impractical.

It was difficult to predict the issues that arose with the provision of the interventions themselves. More discussion before go-live with the Service Provider staff responsible for delivering services might have helped with anticipating the difficulties for example, surrounding advice-giving. This would have enabled the Provider Training Workshops to take place earlier. Providers particularly appreciated the provision of information during the training about the rationale behind the various trial procedures and about the evaluation.

- A future trial should attempt to anticipate difficulties with service provision via discussion with staff before go-live, and apply the knowledge gained in early training (preferably just before or at go-live) of provider staff.

- A bedding-in/piloting period should be considered for future trials where the first few months of live-running are accepted from the start as part of the development phase. This period would be used to identify and iron-out problems.

- Training (and other forums) should always provide the rationale for procedures, as this makes it easier to gain buy-in from staff.

- Early training should give detailed information on the evaluation, both to aid understanding and to focus the attention of provider staff on the trial as a research study.
Given the powerful forces working on staff to ‘cross the line’ between the health and workplace interventions as concerns advice-giving, it seems likely that a good deal of this took place. The ability of the trial to uncover indications of differential effectiveness of a health versus a workplace focus is likely to have been diminished by this slippage in the design. However, contamination in terms of treatments was probably less widespread and so what we can learn about the two models individually appropriately reflects, in one case, a predominantly workplace-focused approach and, in the other case, a predominantly health-focused approach.

- Future trials should consider the issue of advice-giving before go-live and in consultation with appropriate provider staff. Depending on the context, it might be more workable to allow advice-giving to be cross-cutting while treatments themselves are confined to the intervention.

- Serious thought should be given as to whether a four-way trial is necessary, or whether a two-way trial would give the same results, with lower risk of contamination. This particularly applies when it is hard to be clear exactly what help or advice somebody gets.

The wind-down period did not appear to have a significant effect on the treatments delivered. Some treatments were speeded up or delivered more intensively than usual and the more lengthy treatments were not possible in a few cases. Finally, providers were unable to offer return-to-work support for those returning right at the end of the trial, although they referred them to other agencies where possible. Apart from this, it seems that the later trial entrants received substantially the same service as earlier ones.

Providers stressed the importance of effective planning in preparing for wind-down. It is necessary to consider the impact on treatments, staffing levels, changing workloads, finances, systems and record-keeping. Understandably, wind-down procedures were not considered in detail until the end of the trial was approaching, but it would have been preferable to plan for these at the set-up stage. For example, providers would have benefited from advance knowledge of the requirements for the storage of records, erasing of data, redirection of contacts and data provision.

- Future trials should design wind-down procedures in detail at the set-up stage to enable providers to adequately plan for this stage.

9.4 Management and communication

A number of problems were encountered which were associated with the management of the trial and with communication. The evidence suggests that addressing the following points may improve future trials.

- Future trials should consider how an identifiable and accessible management structure can be tailored to best fit that particular trial, rather than attempting to fit the trial into a pre-existing structure.
• Turnover in the management team should be kept to a minimum if possible.
• A ‘partnership’ approach to communication should be considered in the future, seeking consultation from an early stage with all those involved.
• Clearly defined two-way channels of communication need to be set up right at the start of the trial. Dissemination of information should be proactive and timely.
• Members of the management team should consider making regular personal visits to providers to facilitate communication and working relationships, and avoid any impression of a ‘top down’ approach.
• It may be difficult to provide exact details at the start of a trial, but provider staff are likely to benefit from receiving more information at this point on the evaluation, especially where this involves asking them for information (such as a cost-benefit analysis). This benefit needs to be weighed against the danger of being too prescriptive at the start, and then not having the flexibility to make additional information requests should these prove necessary.

9.5 The Management Information System

Providers set up their own systems for recording the management information required by the trial. However, as this was not an area of expertise for them, they found it a difficult and costly task and would have preferred a centralised database to be used by all providers. This would have prevented duplication of effort and inconsistencies between providers, and the difficulties and delays that the Department for Work and Pensions (DWP) experienced when requesting that providers made changes to their databases.

Earlier and more detailed training for all staff involved with the collection and entering of data could have solved the difficulties understanding how to record their activities in the system. Without this, staff used different definitions for data entry which ultimately led to data of varying quality. The training also needed to allow for two-way communication to identify genuine difficulties recording activities to allow small improvements to be made at an early stage. These small changes would have been welcomed by staff but the more fundamental changes implemented at a very late stage in the trial seemed to cause more difficulties than were solved. Rather than improving data quality, the change generated a substantial amount of extra ‘administrative’ work and affected staff morale. With hindsight, the high initial cost anticipated to create a centralised database is likely to have been worthwhile (both in terms of time and money).

There was little enthusiasm from the staff for collecting and entering the information in the system. The task was seen as onerous and not something that they should have been responsible for, which often translated into data not being collected. Where there was acceptance of its high value for the research considerable efforts were made to try to overcome the difficulties.
• We recommend that the database to be used for evaluation and management information purposes be developed and controlled centrally for any future trials.

• The development needs to include consultation of all interested parties including the data entry staff and the evaluation team, sufficient training in its use before ‘go live’, and testing of the output to ensure that it meets the evaluation needs.

• Careful thought should be given in designing the data collection to achieve the right balance between the natural desire of the research team to collect information in great detail, and the practical limitations of what providers are willing to do.

• Substantial changes during live running can increase work loads and affect morale and thus should be avoided. However, small changes made in the early stages can increase data quality.

• Future trials should consider whether data recording can be incentivised to improve the quality, particularly if the data are not collected routinely or are recorded in a separate system.

9.6 Evaluation

9.6.1 Bias

One of the aims of the evaluation of the trial procedures is to allow us to assess to what extent the measures of impact derived from the trial will be unbiased, or at least very close to unbiased. There are a number of ways that bias could have been introduced into the trial including if:

• the allocation to groups was not random;

• being allocated to the Control Group affects their behaviour;

• there was substantial cross-contamination;

• there is differential non-response to the survey collecting the outcome measures.

These issues have been discussed separately in the report. From the earlier discussions it can be concluded that there is unlikely to be any bias through incorrect random allocation (see Section 5.6). It will be difficult to understand the impact of the allocation on the Control Group (see Section 5.5) and inevitably the possibility of some change in behaviour cannot be ruled out although their behaviour will have been recorded in the Outcome Survey (OCS). There is a possibility that the cross-contamination that was observed (see Section 6.10), could introduce bias that could affect the measurement of the impact of the trial. This will be examined explicitly when the impact is measured, and an adjustment made to the final estimates if appropriate. A thorough analysis of the non-response to the OCS will be carried out before the impact is measured. Some non-response adjustments are likely to be made to the final estimates, which should help to reduce any non-response bias.
• Consideration should be given at the start of any future trial about how best to reduce the level of non-response among the Control Group, perhaps by using incentives. It is open to debate whether this would best be done by offering higher incentives to this group and whether this would be considered ethical.

9.6.2 Research Advice role

The Research Advice role was essential for ensuring that providers and the Contact Centre understood and followed the trial’s procedures. It was rightly a flexible role with the ability to respond and deal with problems and information needs as they arose. However, its juxtaposition between the providers and DWP led to some conflicts within the role and possibly added to communication difficulties by lengthening lines of communication further (as the Research Advisers could not make decisions independently but had to refer queries to DWP).

The Research Advisers were not based on providers’ premises, but visited once every three to four months throughout the trial. For more frequent visits to have taken place, this element of the evaluation would have required a larger budget. This had some disadvantages in that providers tended not to be proactive in seeking advice, so the relatively long gap between visits meant that queries were not always put to the advisers. It also meant that it would have been easy for providers to present only their ‘best face’ during the visits.

• The Research Advice role would need to be repeated in some form in any future trial, as it performs the necessary function of ensuring that the trial procedures are followed and in evaluating the overall running of the trial.

• However, this role needs further consideration for future trials, both in terms of its position in the management hierarchy and communication structure, decision-making powers, and location.

• If not based on provider premises, the Research Advisers need to promote active and regular communication between themselves and providers.

To conclude, the Job Retention and Rehabilitation Pilot (JRRP) trial has shown that screening and random assignment can be conducted effectively and ethically in this context. The experience of running this trial provides many lessons that future randomised controlled trials can draw on in reaching the most effective design in this and other policy areas.
Appendix A
Survey of controls and screened-outs methodology

The Survey of Screened-Outs and Controls (SoSOC) was a telephone survey of trial entrants who were randomised to the Control Group and people who had called up to join the trial but were screened-out as not at risk of losing their job. The latter group did not include those who were ineligible to take part in the trial25.

Conducted by the National Centre for Social Research’s (NatCen’s) Telephone Unit, the survey’s main aim was to provide an estimate of the deadweight rate of the trial, to give an early indication of the effectiveness of the screening tool. The deadweight measured by the survey is a return to work (of any length) amongst the controls at 28 weeks after first going off sick from work. The deadweight measure was collected via a week-by-week work history going back to the date that volunteers first went off sick before they phoned to join the trial. The survey also collected information about volunteers’ demographics, household, financial situation, health, attitudes to work and their experiences of screening and randomisation. Where possible, the current activity of non-respondents was also recorded to maximise the proportion whose deadweight status could be estimated.

In total, 857 cases were issued, consisting of 689 control and 168 screened-out volunteers. Productive interviews were conducted with 80 per cent of controls and 74 per cent of screened-outs. The difference in response rates between groups is not statistically significant. The average interview length was 15 minutes for controls and 20 minutes for screened-outs, the difference being because the latter were asked some questions that the Controls would not be asked until the Outcome Survey (OCS)(on attitudes, bridges and barriers to work and benefits).

Data from this survey presented in this report is weighted.

25 That is those who did not live and work within the designated areas, or who were within 18 months of planned retirement, or had not been off work for between six and 26 weeks.
Appendix B
Participant profile

The demographic characteristics of the trial participants are presented below. Data was taken from the screening questionnaire responses. Participants are the sub-group of volunteers that were successfully screened and randomised correctly.\textsuperscript{26}

Table B.1 Randomisation group, by area

<table>
<thead>
<tr>
<th>Randomisation group</th>
<th>xiii</th>
<th>xiv</th>
<th>xv</th>
<th>xvi</th>
<th>xvii</th>
<th>xviii</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>51</td>
<td>86</td>
<td>91</td>
<td>130</td>
<td>173</td>
<td>179</td>
<td>710</td>
</tr>
<tr>
<td>Work</td>
<td>52</td>
<td>87</td>
<td>91</td>
<td>130</td>
<td>174</td>
<td>178</td>
<td>712</td>
</tr>
<tr>
<td>Combined</td>
<td>51</td>
<td>86</td>
<td>91</td>
<td>131</td>
<td>175</td>
<td>179</td>
<td>713</td>
</tr>
<tr>
<td>Control</td>
<td>51</td>
<td>87</td>
<td>91</td>
<td>130</td>
<td>173</td>
<td>178</td>
<td>710</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>205</td>
<td>346</td>
<td>364</td>
<td>521</td>
<td>695</td>
<td>714</td>
<td>2,845</td>
</tr>
</tbody>
</table>

Table B.2 Length of time off sick (current spell)

<table>
<thead>
<tr>
<th>Time off sick</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-12 weeks</td>
<td>1,637</td>
<td>58%</td>
</tr>
<tr>
<td>13-19 weeks</td>
<td>766</td>
<td>27%</td>
</tr>
<tr>
<td>20-26 weeks</td>
<td>439</td>
<td>15%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,842</td>
<td>100%</td>
</tr>
</tbody>
</table>

\textsuperscript{26} Six records have been removed. These were records that should not have been sent for randomisation (n=4), or clients had been identified as not having completed their participation in the trial and therefore had been reallocated to the same group that were removed to avoid double-counting (n=2).
### Table B.3  Hours worked before went off sick

<table>
<thead>
<tr>
<th>Hours worked</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-34 hours</td>
<td>737</td>
<td>26%</td>
</tr>
<tr>
<td>35+ hours</td>
<td>2,098</td>
<td>74%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,835</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

* n=10 missing

### Table B.4  Type of dependents caring for at home

<table>
<thead>
<tr>
<th>Type of dependents</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children &lt; 16 years</td>
<td>222</td>
<td>87%</td>
</tr>
<tr>
<td>Older relatives</td>
<td>7</td>
<td>3%</td>
</tr>
<tr>
<td>Disabled children (any age)</td>
<td>6</td>
<td>2%</td>
</tr>
<tr>
<td>Other adults similar age</td>
<td>19</td>
<td>7%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>254</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

* n=12 missing

Data only for those who have dependants, and only for the sub-group of clients who joined the trial after 28 June 2004.

### Table B.5  Employment status – employee/self-employed

<table>
<thead>
<tr>
<th>Employment status</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permanent employee</td>
<td>2,681</td>
<td>94%</td>
</tr>
<tr>
<td>Fixed-term contract employee</td>
<td>63</td>
<td>2%</td>
</tr>
<tr>
<td>Casual employee</td>
<td>11</td>
<td>0%</td>
</tr>
<tr>
<td>Self-employed</td>
<td>88</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,843</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

* n=2 missing

### Table B.6  Type of employer – private or public company

<table>
<thead>
<tr>
<th>Type of employer</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private</td>
<td>1,231</td>
<td>43%</td>
</tr>
<tr>
<td>Public</td>
<td>1,505</td>
<td>53%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>105</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,841</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

* n=4 missing
### Table B.7  Size of employer

<table>
<thead>
<tr>
<th>Number of employees</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-49</td>
<td>324</td>
<td>14%</td>
</tr>
<tr>
<td>50-249</td>
<td>261</td>
<td>11%</td>
</tr>
<tr>
<td>250+</td>
<td>1,794</td>
<td>75%</td>
</tr>
<tr>
<td>**Total ***</td>
<td><strong>2,379</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

* n=466 missing

Note that there are a high number of cases that do not have an employer size (where value equals zero). These cases might not all be missing but there is no way of distinguishing between true zeros and missing.

### Table B.8  Whether likes job or not

<table>
<thead>
<tr>
<th>Whether likes job</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>2,374</td>
<td>84%</td>
</tr>
<tr>
<td>No</td>
<td>277</td>
<td>10%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>185</td>
<td>7%</td>
</tr>
<tr>
<td>**Total ***</td>
<td><strong>2,836</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

* n=9 missing

### Table B.9  Supervisor/manager understanding about sickness absence

<table>
<thead>
<tr>
<th>Supervisor/manager understanding</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1,797</td>
<td>65%</td>
</tr>
<tr>
<td>No</td>
<td>501</td>
<td>18%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>478</td>
<td>17%</td>
</tr>
<tr>
<td>**Total ***</td>
<td><strong>2,776</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

* n=9 missing (not self-employed)

### Table B.10  Whether able to do job in six months time

<table>
<thead>
<tr>
<th>Able to do job in 6 months</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1,117</td>
<td>39%</td>
</tr>
<tr>
<td>No</td>
<td>391</td>
<td>14%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>1,331</td>
<td>47%</td>
</tr>
<tr>
<td>**Total ***</td>
<td><strong>2,839</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

* n=6 missing
### Table B.11  Whether feel able to return to work after current leave

<table>
<thead>
<tr>
<th>Return to work after current sick leave</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>160</td>
<td>21%</td>
</tr>
<tr>
<td>No</td>
<td>266</td>
<td>36%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>322</td>
<td>43%</td>
</tr>
</tbody>
</table>

Total * 748 100%

* n=3 missing

Data only for the sub-group of clients who joined the trial after 28 June 2004.

### Table B.12  Time off sick over last 12 months

<table>
<thead>
<tr>
<th>Time off sick in last year</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 3 months</td>
<td>1,269</td>
<td>45%</td>
</tr>
<tr>
<td>3-6 months</td>
<td>1,276</td>
<td>45%</td>
</tr>
<tr>
<td>6-9 months</td>
<td>169</td>
<td>6%</td>
</tr>
<tr>
<td>More than 9 months</td>
<td>128</td>
<td>5%</td>
</tr>
</tbody>
</table>

Total * 2,842 100%

* n=3 missing

Forty-one per cent of those above only had their current period of sickness during the last 12 months.

### Table B.13  Suffered with panic attacks recently

<table>
<thead>
<tr>
<th>Panic attacks recently</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1,005</td>
<td>35%</td>
</tr>
<tr>
<td>No</td>
<td>1,787</td>
<td>63%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>49</td>
<td>2%</td>
</tr>
</tbody>
</table>

Total * 2,841 100%

* n=4 missing
### Table B.14  Ever seen doctor for anxiety or depression

<table>
<thead>
<tr>
<th>Doctor for anxiety/depression</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1,574</td>
<td>55%</td>
</tr>
<tr>
<td>No</td>
<td>1,251</td>
<td>44%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>15</td>
<td>1%</td>
</tr>
</tbody>
</table>

**Total *:** 2,840 100%

* n=5 missing

### Table B.15  Currently waiting for treatment

<table>
<thead>
<tr>
<th>Waiting for treatment</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>2,279</td>
<td>80%</td>
</tr>
<tr>
<td>No</td>
<td>543</td>
<td>19%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>19</td>
<td>1%</td>
</tr>
</tbody>
</table>

**Total *:** 2,841 100%

* n=4 missing

### Table B.16  Reasons off sick – health reasons

<table>
<thead>
<tr>
<th>Health conditions include</th>
<th>Frequency</th>
<th>Percent</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular disease</td>
<td>358</td>
<td>13%</td>
<td>2,845</td>
</tr>
<tr>
<td>Musculo-skeletal problems</td>
<td>1,246</td>
<td>44%</td>
<td>2,845</td>
</tr>
<tr>
<td>Mental health problems</td>
<td>1,006</td>
<td>35%</td>
<td>2,845</td>
</tr>
</tbody>
</table>
### Table B.17 Reasons off sick – non-health reasons

<table>
<thead>
<tr>
<th>Non-health reasons off sick</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pain</td>
<td>258</td>
<td>9%</td>
</tr>
<tr>
<td>Mobility problems</td>
<td>253</td>
<td>9%</td>
</tr>
<tr>
<td>Loss of confidence</td>
<td>238</td>
<td>8%</td>
</tr>
<tr>
<td>Fear that work could do harm</td>
<td>118</td>
<td>4%</td>
</tr>
<tr>
<td>Bullying at work</td>
<td>117</td>
<td>4%</td>
</tr>
<tr>
<td>Uncomfortable work pressure</td>
<td>51</td>
<td>2%</td>
</tr>
<tr>
<td>Family conflict</td>
<td>41</td>
<td>1%</td>
</tr>
<tr>
<td>Carer responsibilities (including children)</td>
<td>39</td>
<td>1%</td>
</tr>
<tr>
<td>Conflict with line management</td>
<td>31</td>
<td>1%</td>
</tr>
<tr>
<td>Transport problems</td>
<td>28</td>
<td>1%</td>
</tr>
<tr>
<td>Financial problems</td>
<td>27</td>
<td>1%</td>
</tr>
<tr>
<td>Phobias</td>
<td>15</td>
<td>1%</td>
</tr>
<tr>
<td>Industrial dispute</td>
<td>4</td>
<td>0%</td>
</tr>
<tr>
<td>Other</td>
<td>35</td>
<td>1%</td>
</tr>
<tr>
<td><strong>None</strong></td>
<td>1,679</td>
<td>59%</td>
</tr>
<tr>
<td>**Total *</td>
<td>2,842</td>
<td></td>
</tr>
</tbody>
</table>

* n=3 missing

Note that up to four non-health reasons could be chosen above.
Appendix C
Assessing the screening

Recruitment for script research

Recruitment was carried out using ‘snowballing techniques’: members of the National Centre for Social Research (NatCen) Research Advice team called upon a few selected NatCen survey interviewers to enquire amongst their friends and acquaintances to identify suitable respondents according to the specified eligibility criteria. These people were then given a letter outlining the study and asked if they would agree to be contacted by the research team. The research team contacted volunteers by phone to arrange a time for interview. Volunteers were recruited from two non-pilot areas: North London and Leeds.

Table C.1  Achieved sample for Contact Centre script research

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Length of time off sick</th>
<th>Less than 6 weeks</th>
<th>6 weeks to 6 months</th>
<th>more than 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age ranges</th>
<th>Below 30</th>
<th>30-50</th>
<th>Over 50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Occupation group</th>
<th>Professional</th>
<th>Clerical</th>
<th>Manual</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

The interview schedule, which was drawn up in conjunction with the Department for Work and Pensions (DWP), consisted of parts of the Contact Centre script to be read out to respondents followed by questions to elicit recall and understanding and to explore respondent processes and views. It was designed to be semi-structured in format for ease and speed of analysis.
Interviews were conducted face-to-face rather than over the telephone because it was felt that it would be easier to explain and administer the format of reading and questioning better on a more personal basis. The format proved successful and, wherever possible, two members of the research team attended the interview: one to read out the script and the other to conduct the interview. Interviews, which generally lasted about 90 minutes, were tape recorded. The data was subsequently transferred directly from the tape into a computerised analytical framework. All volunteers were given £15 by way of thanks for their time and help.

Fieldwork was carried out in the weeks of 17 and 24 November 2003 at a venue of the respondent’s choice: usually their home although a few preferred to be interviewed on NatCen premises. A presentation of findings was made to DWP at NatCen on 15 December 2003.

Screening recordings – selected calls

**Table C.2 Selected calls**

<table>
<thead>
<tr>
<th>Outcome of screening</th>
<th>Total</th>
<th>Month of screening</th>
<th>Pilot area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility not confirmed</td>
<td>5</td>
<td>October 2003</td>
<td>SH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>November 2003</td>
<td>BI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>December 2003</td>
<td>SH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>January 2004</td>
<td>GL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>February 2004</td>
<td>TY</td>
</tr>
<tr>
<td>Ineligible</td>
<td>7</td>
<td>August 2003</td>
<td>TY</td>
</tr>
<tr>
<td></td>
<td></td>
<td>December 2003</td>
<td>BI, SH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>January 2004</td>
<td>SH*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>February 2004</td>
<td>WK, WK</td>
</tr>
<tr>
<td>Screened-out (not at risk)</td>
<td>6</td>
<td>May 2003</td>
<td>BI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>June 2003</td>
<td>SH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>July 2003</td>
<td>WK</td>
</tr>
<tr>
<td></td>
<td></td>
<td>January 2004</td>
<td>BI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>February 2004</td>
<td>GL, BI</td>
</tr>
<tr>
<td>Screened in but refused consent to be randomised</td>
<td>3</td>
<td>July 2003</td>
<td>SH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>December 2003</td>
<td>TE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>January 2004</td>
<td>SH</td>
</tr>
<tr>
<td>Screened in &amp; randomised</td>
<td>7</td>
<td>April 2003</td>
<td>BI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>July 2003</td>
<td>SH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>October 2003</td>
<td>TY</td>
</tr>
<tr>
<td></td>
<td></td>
<td>November 2003</td>
<td>BI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>January 2004</td>
<td>SH, GL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>February 2004</td>
<td>BI</td>
</tr>
</tbody>
</table>

* Recording not found
Appendix D
SoSOC non-response weighting

An initial analysis of characteristics of respondents and non-respondents appeared to show some differential response. Whilst this showed that there may be a number of characteristics related to response, these may be correlated. A multivariate analysis was necessary to look at the characteristics simultaneously.

Non-response was modelled in Stata, using a logistic model. The dependent variable had the value of one if the client responded and zero if they did not respond. The model was estimated in a stepwise fashion to select only the strongest factors related to response. The factors collected at screening included:

- pilot area;
- gender;
- age;
- marital status;
- whether have dependent children;
- ethnicity;
- highest educational qualification;
- income;
- type of job (measured by Standard Occupational Classification code);
- health condition (cardiovascular, musculo-skeletal, mental health);
- risk score (four categories; screened-out, screened in score split into tertiles).

Only health condition and risk score were selected into the model. This implies that once health condition and risk score have been accounted for there are no significant differences in response by any other characteristic included in the model.
Appendix E
Randomisation notification letters

Intervention Group notification letter (font size reduced compared to original).

Dear «A03_First_Name»,

Recently you contacted us about «Provider_Letter_Text1», a research project designed to find out what support helps people who are worried about losing their job and are off work because of ill health or a disability. As we described to you, in order to test whether introducing a new way of organising services helps people stay in work, we need to compare the experiences of those who get these new kinds of service and those who don’t. This is so we can find out if changing the way we give you support and assistance is better than the way this is being done at the moment. To be fair we divided people at random into groups, 3 in 4 people get the new kinds of service.
You have been selected to be in a group that will get the new way of organising services and you have a very important role to play in this project. We will contact you very soon. You may already have been contacted. You will be given more information about the type of help that is being offered to you. It will be another opportunity for you to ask us any questions about the project. We will ask you about what you need so that together we can decide on a plan of action. If you agree to the plan of action and are happy to continue to be part of the research project you will then get the help on your plan. We will also ask you if we can tell your doctor that you are taking part in this project. You should still continue to see your doctor if they have asked to see you again and you may take up any other help you are offered if you wish to.

We would like to talk to you in a few months time and this will help us find out whether «Provider_Letter_Text1» works. A trained interviewer from the research team will contact you. You do not have to take part in the interview if you prefer not to, but the interview will be a chance for you to tell us about your experiences. We will ask you about your health, your work and related events. Your views will influence our conclusions about which services we need to introduce.

We appreciate your help and would like to thank you for agreeing to take part in this study. Doing so will help us to design better services to help people who develop an illness or disability to return to work and stay in work.

If you have any questions or concerns please contact NatCen on 0800 XXXXXXX between 9am and 5pm Monday to Friday.

Yours sincerely,

Chris Massett

(Research Team)
Dear «A03_First_Name»,

Recently you contacted us about «Provider_Letter_Text1», a research project designed to find out what support helps people who are worried about losing their job and are off work because of ill health or a disability. You have been placed in a group to receive existing support already in your community rather than the alternatives being tried out for the first time by the project. As we described to you, in order to test whether introducing a new way of organising services helps people stay in work, we need to compare the experiences of those who get these new kinds of service and those who don’t. This is so we can find out if changing the way we give you support and assistance is better than the way this is being done at the moment. To be fair we divided people at random into groups, 3 in 4 people get the new kinds of service.

Although you have not been selected to receive one of the new kinds of service you have a very important role to play in this study. You are in the group that we need to talk to so we can compare different experiences to see what really works, in your case the standard support available in your community. You should continue to see your doctor if they have asked to see you again and you can take up any other help you are offered if you wish to.

We would like to talk to you in a few months time. A trained interviewer from the research team will contact you. You do not have to take part in the interview if you prefer not to, but the interview will be a chance for you to tell us about your experiences. We will ask you about your health, your work and related events. Your views will influence our conclusions about what services we need to introduce.
We appreciate your help and would like to thank you for agreeing to take part in this study. Doing so will help us to design better support to help people who develop an illness or disability, to return to work and stay in work.

If you have any questions or concerns please contact NatCen on 0800 XXXXXXX between 9am and 5pm Monday to Friday.

Yours sincerely,

Chris Massett
(Research Team)
Appendix F
Randomisation program checks

Initial checks:

- data formats were checked to ensure they met the original specification, this was to help to identify corrupt data files and prevent incorrect data being processed and transferred to the providers;
- if an entrant had previously been randomised but not finished their current spell in the pilot they were reallocated to same group;
- if an entrant had previously been randomised but had completed their previous spell then they were treated as a new entrant (except the Control Group who should have been reallocated to the same group27);
- the output files created each time a file was processed (containing the notification letters and provider output files) had to be moved to a different location before the next file was processed, this was to help to prevent output files being muddled and to act as a reminder to check that all tasks had been completed from the previous file;
- files that had previously been processed could not be re-processed;
- on any one day the second file received from the Contact Centre could not be processed until the first file had been processed.

27 Unfortunately two Control Group clients were subsequently randomised into an intervention group because they were not correctly identified at the screening and were not given the same identification number.
Extra checks:

- a manual check of the content of the received file was made to confirm it was empty when the program did not detect any callers to be randomised;

- cases were only randomised if they had consented to randomisation, the Contact Centre should have only transferred them if consent had been given but the check was repeated because it was liable to error (note that consent data was never added to the file sent from the Contact Centre so that this check could not be implemented);

- confirmed (via the unique identification number) that the case hadn’t been randomised previously to prevent duplicate information being accepted by the program and cases being randomised twice incorrectly;

- confirmed (via name, date of birth and contact details) that the case hadn’t been randomised previously but failed to be identified by the Contact Centre, to prevent cases being randomised twice incorrectly (but note that this check was not 100 per cent accurate because the program would not identify information that was the same but not identical);

- confirmed that the case was eligible with respect to geography, the Contact Centre should only have transferred if eligible cases but this check was repeated to prevent ‘out of area’ ineligible cases being randomised incorrectly;

- files not being processed was reduced by setting a maximum number of days between consecutive files;

- files had to be processed in exact consecutive order (dated) so that missed files could not be processed out of sequence e.g. if processed 5 June files 1 and 2, 7 June file 1, then would not be able to process any files from 6 June, this was to ensure that files were processed in order of receipt and to help to identify if any files had been missed.
Appendix G
Reasons for calling the information line

Up to the end of the recruitment period (December 2004), 127 clients had used the information line. The reasons for calling are given in the tables below. In addition to the clients shown below, eight callers left no information or contact details, and a further caller refused to give any information about themselves. Some clients called more than once for different reasons.

Table G.1  Reason for calling the information line – Intervention Groups

<table>
<thead>
<tr>
<th>Reason</th>
<th>Frequency</th>
<th>Other details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not been contacted by provider</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>Couldn’t make appointment with provider</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Wanting to contact provider staff</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Lost provider’s contact details</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Wanting to know what was to happen next</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Needed reassurance about specific detail of service</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Querying contact arrangements with provider</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Gave further contact details</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Hadn’t received randomisation notification letter</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Needed randomisation notification letter clarifying</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Worried because provider warned not been able to get</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>in touch with them</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Base</td>
<td>90</td>
<td></td>
</tr>
</tbody>
</table>
### Table G.2  Reason for calling the information line – Control Group

<table>
<thead>
<tr>
<th>Reason</th>
<th>Frequency</th>
<th>Other details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upset about allocation to Control Group</td>
<td>15</td>
<td>One client’s GP also called, five withdrew from trial, one wants to re-apply to change groups</td>
</tr>
<tr>
<td>Gave new contact details</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Needed randomisation notification letter clarifying</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Wanted to withdraw and have details removed</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Hadn’t received randomisation notification letter</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Wanted to re-apply to change groups</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Wanted support</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Felt misled by Contact Centre information</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Base</td>
<td>32</td>
<td></td>
</tr>
</tbody>
</table>
References


Prime Minister’s Strategy Unit (2004), Improving the Life Chances of Disabled People, London: Cabinet Office.

