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Attitudes towards
participating in fMRI
studies amongst
participants in a
birth cohort study.

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November 2010

**Understanding Individual Behaviour
Exploratory Network:**

**Investigating the genetic, social and
neuropsychological influences on
individual differences in memory using
a lifecourse approach.**

**Attitudes towards participating in fMRI
studies amongst participants in a birth
cohort study.**

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1 Introduction

1.1 Background

The use of Magnetic Resonance Imaging (MRI) in research studies is becoming increasingly common. Whilst research participants might find the experience of being scanned somewhat noisy or claustrophobic the risk of actual harm being caused by the process is minimal. However, research by Morris et al (2009) suggests that in approximately one in forty scans the process reveals pathological problems (or potential problems) which participants were previously unaware of and research by Iles et al (2004a) confirms that the prevalence of incidental findings rises with age. This raises important questions about the extent to which information about such problems should be fed back to participants. At present the guidelines which exist are inconsistent and incomplete (Booth et. al, 2010) and as such current practice varies between different research studies and institutions (Iles et. al 2004b).

A sub-sample of National Child Development Study members were recently invited to participate in a pilot study which sought to investigate the potential of conducting neuropsychological assessments with purposive subsamples of the British Birth Cohort Studies. On completion of the assessments participants completed a short questionnaire which included a number of questions gathering views about participating in research studies involving MRI scanning.

The pilot was conducted by an exploratory network led by the Centre for Longitudinal Studies (CLS). The network included researchers from the Department of Experimental Psychology at Cambridge University, the Social, Genetic and Developmental Psychiatry Centre at King's College London and the Institute of Psychiatry at King's College London. The project was funded under the Understanding Individual Behaviours - Exploratory Network (UIBEN) cross council programme. The project ran from July 2009 to September 2010.

When planning the pilot study consideration was given to the inclusion of functional MRI scanning for a subset of participants, but in the end this was not feasible. The network did, however, provide an opportunity to discuss the ethical challenges associated with conducting this kind of research and one of the network's outputs is a full ethical review of the issues raised by the use of MRI scanning (and DNA analysis) in birth cohort studies (Richards, 2010).

This review makes it clear that there is currently a lack of empirical evidence on what research participants themselves might think about participating in this kind of study and the expectations or preferences they might have in terms of feeding back information on incidental findings which might be detected during the scanning process. One USA study exploring this issue found that 90% would want to be informed of *all* incidental findings, regardless of whether they be considered significant (Kirshen et. al, 2006). However, participants in this study had all had previous experience of participating in some form of MRI research study so their views may have been influenced by their experiences. In summarising the views of

the pilot study participants this report makes a valuable contribution to this important area of research.

1.2 The Understanding Individual Behaviour Exploratory Network

The initial aims of the network were to investigate the genetic, social and neuropsychological influences on: i) individual differences in impulsivity and ii) individual differences in memory using a lifecourse approach. However, the work conducted has focussed primarily on mid-life memory and how this relates to experiences and behaviour earlier in the lifecourse.

The network brought together researchers from a number of disciplines within the social sciences, as well as experts from behavioural genetics, neuropsychology and neuroimaging, and those with an established interest in research ethics and sought to apply ideas and techniques at the cutting edge of behavioural genetics and to capitalize on the research resource represented by the longitudinal British Birth Cohort Studies.

1.3 The pilot study

A sub-sample of 133 National Child Development Study members living in and around Cambridge who achieved a range of scores on the cognitive assessments included in the age 50 survey in 2008 were invited to a research centre at the University of Cambridge to complete a 90 minute session involving the repetition of the assessments completed at age 50, a battery of 5 CANTAB (Cambridge Neuropsychological Test Automated Battery) assessments and a short questionnaire. Assessments were conducted with 45 individuals.

The pilot study aimed to recruit individuals with particular cognitive ability trajectories between childhood and mid-adulthood. Childhood cognitive ability was measured using the General Ability Test (GAT) which was conducted at age 11. Adult cognitive ability was measured using the cognitive assessments conducted at age 50.

Three groups of individuals were identified for potential inclusion in the pilot study. The three groups were constructed by using age 11 GAT score to predict the summed score on the immediate and delayed word-list recall tests conducted at age 50 (Brown et. al, 2010) using ordinary least squares regression.

- 1) The main experimental group or '**Decline**' group showed a decline in memory at the age of 50 as compared to that predicted by childhood cognitive scores. The group were selected on the basis that their summed score on the immediate and delayed word-list recall tests conducted at age 50 was more than one standard deviation lower than was predicted from their GAT score.

This group was then matched with two control groups:

- 2) **Control group 1: 'Consistent high scorers'** – This group were matched to the experimental group on childhood cognitive ability level, but did not exhibit any signs of decline.
- 3) **Control group 2: 'Consistent low scorers'** – This group were matched to the experimental group on their age 50 cognitive ability (as measured by the summed score on the two word-list recall tasks), but had different cognitive ability levels in childhood (most likely having low cognitive ability throughout their lives).

A fuller discussion of the motivation for conducting the pilot study and its substantive findings can be found here (Knight et al, 2010). A description of the sample design, the assessments, the fieldwork procedures, the response rate and feedback from participants on their experience of taking part can be found here (Brown et al, 2010).

2. Results

2.1 Previous experience of being scanned

Respondents were asked whether they had previously ever been scanned in an MRI scanner and if so whether this was for clinical diagnosis and/or as part of a research study. In total seven of the 45 (16%) had previously been scanned and in all cases this had been for clinical diagnosis; no respondents had participated in a research study involving the use of MRI scanning.

As Table 1 below shows, 6 of the 7 individuals who had previously been scanned were males and 1 was female. Four of the 7 individuals were defined as belonging to the 'consistent achiever' group, 2 were from the 'decline' group and 1 was from the 'consistently low achiever' group.

Table 1: Previous experience of being scanned

	Yes		Base
	N	%	
All	7	15.9	44
Decline	2	12.5	16
Consistently high scorers	4	26.7	15
Consistently low scorers	1	7.7	13
Men	6	24.0	25
Women	1	5.3	19

2.2 Likely participation and views on feedback of information

After establishing whether or not respondents had previously been scanned the questionnaire moved on to ask about whether participants would be prepared to take part in a study involving fMRI scanning (if they were asked to do so by CLS). The researcher used a pre-prepared script to explain about the fact that participation in such a study could potentially result in the scan revealing potentially serious health problems:

“Like faces, brains come in all shapes and sizes, so that there are many normal variations of what the scan shows. It is possible, though, that a scan could reveal something that suggests that there could be a more serious problem. This is estimated to happen in about one in forty scans. However, for the great majority of people who are scanned in research studies no significant problems will be observed.”

The script then went on to explain that participants in these kinds of studies might have different views about the feedback that they would like/expect if they participated in an MRI study:

“People may differ in their views about feedback from research fMRI studies. Some people would like to know if their scan result reveals anything that might suggest they might have a serious problem, regardless of whether this may turn out to be treatable or not. Others would prefer only to know if the scan revealed clear evidence of a serious problem that is likely to be treatable. Some do not want any feedback whatever the scan may reveal. They prefer, should they develop a serious condition, to wait until they have symptoms and then to seek a diagnosis and treatment from a doctor at that time.”

After being given an opportunity to ask further questions respondents were asked about whether they would be prepared to take part in an fMRI study and the kinds of feedback they would expect to receive. The options which were presented to participants were:

1. I would not be prepared to take part in an fMRI research study
2. I would be prepared to take part in an fMRI study regardless of whether feedback was to be provided.
3. I would **only** be prepared to take part in an fMRI study which provided feedback on **all potential problems** that were observed.
4. I would **only** be prepared to take part in an fMRI study which only provided feedback on potential problems that were considered to be **serious and treatable**.
5. I would **only** be prepared to take part in an fMRI study which provided **no** feedback.

Responses are summarised below in Table 2.

The vast majority indicated that they would be prepared to take part in an fMRI study (95%). Amongst those who suggested that they would participate in an fMRI study (if asked to do so) the majority either stated that they would participate regardless of whether any feedback about potential problems was to be provided (n=19, 43%) or that they would only participate if feedback was to be provided on all potential problems, regardless of whether they were considered to be serious or treatable. A smaller proportion (n=5, 11.4%) suggested that they would only participate in a study which would only provide feedback on potential problems which were considered to be serious and treatable and nobody reported that they would only participate in a study providing no feedback.

The sample size is small and differences between various sub-groups do not, therefore, reach statistical significance. There is an indication that those identified as showing signs of cognitive decline were less likely to suggest that they would participate regardless of whether feedback was to be provided (25% compared with around half of the other two groups) and more likely to suggest that they would only participate in a study which provided feedback on all potential problems (50% compared with around 35% of the other two groups). One could hypothesise that this might result from this group being most concerned about future cognitive decline. Indeed those that reported that they were concerned about developing at least one of

a list of health problems that would affect the nervous system (Parkinson's disease, multiple sclerosis, diabetes, stroke or heart disease) seemed also marginally less likely to report that they would take part regardless of whether feedback was to be provided (although it was the consistently high scorers who were most likely to report being concerned about these future health problems).

There did not appear to be any differences between the views expressed by men and women; general health over the last 12 months also seemed to have little impact on one's preferences in terms of feedback and nor did previous experience of being scanned.

Table 2: Whether would participate in an fMRI study if asked by CLS to do so.

	NO		YES								N
	n	%	Regardless of whether feedback provided		Only if feedback on all potential problems		Only if feedback only provided on problems considered serious and treatable		Only if no feedback provided		
				n	%	n	%	n	%	n	%
ALL	2	4.5	19	43.2	18	40.9	5	11.4	0	0	44
Group Status											
Decline	1	6.2	4	25.0	8	50.0	3	18.8	0	0	16
Consistent high scorers	1	6.7	8	53.3	5	33.3	1	6.7	0	0	15
Consistent low scorers	0	0	7	53.8	5	38.5	1	7.7	0	0	13
Sex											
Male	1	4.0	10	38.5	11	42.3	3	11.5	0	0	25
Female	1	5.3	9	47.4	7	36.8	2	10.5	0	0	19
General health – last 12 months											
Excellent / very good	1	4.2	10	41.7	12	50.0	1	4.2	0	0	24
Good	0	0	6	42.9	6	42.9	2	14.3	0	0	14
Fair / poor	1	16.7	3	50.0	0	0	2	33.3	0	0	6
Previous experience of fMRI scanning?											
Yes	1	14.3	3	42.9	3	42.9	0	0	0	0	7
No	1	2.7	16	43.2	15	40.5	5	13.5	0	0	37
Concern about future health problems affecting the nervous system?											
Yes	1	4.0	9	36.0	10	40.0	5	20.0	0	0	25
No	1	5.3	10	52.6	8	42.1	0	0	0	0	19

Respondents were then given an opportunity to explain the answers they had given in their own words. The key themes were as follows:

Benefits of early detection

The most commonly cited reason for preferring to participate in a study which would provide feedback was the perceived benefit of early detection of potential problems. Of the 42 individuals who suggested that they would participate in an fMRI study, 14 (33%) suggested that one of the reasons that they would be interested in doing so was that they could stand to benefit from the early detection of a potential problem.

Mentioning the benefits of early detection of potential problems was most common amongst those who had stated that they would only take part in an fMRI study which provided feedback on *all* potential problems (n=8, 44%). Typical responses included “... to be pre-warned of any possible problems that may become serious later on in life so that it can be resolved before it does become too serious” and “... if I had something wrong I would rather know it now and so it could be treated early”.

Two individuals (40%) from the group that stated that they would only participate in a study which provided feedback only on problems which were considered serious and treatable and four individuals from the group who said they would participate in a study regardless of whether feedback was to be provided also mentioned the benefits of early detection of problems. The comments made were very similar to those quoted above.

Peace of mind / Reassurance

A slightly more optimistic slant on the above view was that participating in an fMRI study would provide ‘peace of mind’ or reassurance that there were no problems. This reason for wishing to participate was reported by three respondents who, for example, said “*I would like peace of mind that there is nothing wrong*” and “*Would like reassurance that no problems exist*”. All three of these individuals reported that they would only take part in an fMRI study that provided feedback on all potential problems.

Contribution to research

Another motivation for participating in this kind of study was that doing so would contribute to important research. In total 8 of the 42 individuals (19%) who suggested they would participate in an fMRI study stated that this was a reason for doing so. Five of these individuals were from the group who stated that they would take part in an fMRI study regardless of whether feedback on potential problems was to be provided. Comments included: “*I would be happy to undertake a scan both for the benefits of myself and others*” and “*if I had a scan and there was nothing then the*

research would still be useful". Three individuals who stated a preference about the kinds of feedback that they would require if they were to participate also made similar comments, for example "*... any form of research which could help medical science must be beneficial.*"

Loyalty to NCDS

Five respondents (12% of those who said that they would participate in an fMRI study) suggested that they would do so out of loyalty to the NCDS study. Four of these individuals were from the group who suggested they would take part regardless of whether feedback on potential problems was to be provided. One individual, for example, said "*I am a loyal cohort member and I would like to see the study progress*" and another went as far as to say "*I would do anything to help further the NCDS study*".

Family

A small number (n=3) of respondents provided answers which mentioned their family in some way. One respondent recognised that the decision to participate in an fMRI study could have implications for her family and therefore reported that although, in principle, she would have no objections to participating in such a study, the final decision would need to be taken in consultation with her family. Another respondent who was motivated to participate because of the possible benefits of early detection of potential problem went on to explain that the key benefit to her would be that this might potentially provide her with the opportunity to continue being part of her children's lives for longer. Finally one further respondent explained that his father had developed Parkinson's disease in his seventies which had caused great distress to his family. Consequently this respondent was keen to participate, partly because the scan could provide an opportunity to detect potential problems which he himself might face but also because it would be an opportunity to contribute to medical research which might go some way to providing a cure for these kinds of illnesses in the future.

Untreatable conditions

Two participants explicitly stated that they would want to be alerted to all problems, even if they were untreatable. The reason for this was that both respondents felt that knowing in advance about such problems would allow them to prepare. For example, one respondent stated "*... if (the problem) was untreatable, I could work out how to live with it*".

Claustrophobia

The two individuals who stated that they would not be prepared to participate in an fMRI study reported that this was because they were concerned that they would feel claustrophobic, for example, one respondent said "*I think I would be too claustrophobic to do it*".

3 Summary

The analyses presented in this report are based on data collected from a particular sub-sample of National Child Development Study members. It is doubtful whether their views are representative of all members of the study; this group of individuals all live within 60 miles of Cambridge, all were identified as having particular trajectories in cognitive ability between childhood and adulthood, all were still participating in the study at the age of 50 and, most importantly, all agreed to participate in a pilot study which involved them travelling to Cambridge to complete an intensive battery of neuro-psychological assessments. The pilot study had a low response rate (34%) so those that did participate can be thought of as being particularly loyal members of the study.

The great majority of pilot study participants reported that they would be prepared to take part in an fMRI study if asked to do so by CLS. However, if the question had been put to the whole cohort it is likely that this proportion suggesting that this would be the case might have been considerably smaller. Members of the National Child Development Study are used to being 'studied', those still involved in the study have been participating for over 50 years and as such many will have developed a sense of loyalty to the study and a sense of trust in the organisation responsible for the study. The views of members of a long-running cohort study, in terms of the likelihood of agreeing to participate in an fMRI study and their expectations in terms of the information that would be fed back may therefore differ from the wider population.

Focusing on the pilot study participants though, just over half of those who suggested that they would be prepared to participate in an fMRI study stated they would only do so if feedback on potential problems were to be provided. Amongst this group it was far more common to wish for feedback to be provided on *all* potential problems rather than just those which were considered to be serious and treatable.

Just under half of participants suggested that they would take part in an fMRI study even if feedback on potential problems was not to be provided, in many cases because of 'loyalty' to the study. However, adopting the approach of providing no feedback would seem to be a clear breach of the duty of care that researchers have to towards participants, which is arguably particularly great in the case of a long-running cohort study.

None of the pilot study participants suggested that they would only participate in an fMRI study if no feedback was to be provided. However, the sample size was small and it may well be the case that others would feel that this would be the option they would prefer. As is concluded by Richards in the ethical review mentioned earlier (Richards, 2010) it seems therefore that the most appropriate course of action is to ensure that those invited to take part in an fMRI study are provided with all the information needed to firstly make a decision about whether to participate and secondly to make a choice about the nature of the feedback they wish to receive (if any). Views on the nature of feedback desired will differ between individual

participants and as long as sufficient information is provided about the consequences of their decision their wishes should be taken into account.

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