Evaluation of Employment Advisers in Improving Access to Psychological Therapies

June 2018

Short title:	Employment Advisers in IAPT Evaluation
Trial Sponsor:	Work and Health Unit
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SYNOPSIS

Title	Evaluation of increasing the ratio of employment advisers to therapists in IAPT services
Chief Investigator	Rowan Foster IFF Research, 5th Floor, St. Magnus House, 3 Lower Thames Street, EC3R 6HD IAPTevaluation@IFFResearch.com, 020 7250 3035
Background	IAPT services (Improving Access to Psychological Therapies) began in 2008 with the aim of providing psychological therapies for common mental health disorders such as anxiety and depression. Employment Advisers (EAs) were also embedded into IAPT services with the aim of integrating mental health and employment support to improve both work and health outcomes for people. When IAPT services were introduced, a 1:8 ratio of EAs to IAPT therapists was expected; however, there has been considerable differences between services in the actual ratio implemented (with some services operating at a ratio of 1:50). As part of the Spending Review 2015, extra funding was received to employ more EAs to bring the ratio up to the initial 1:8 figure that was proposed. The investment in EAs will be rolled out to 83 Clinical Commissioning Groups (CCGs) in two waves as part of a national pilot. Wave 1 began to receive the additional EAs to fulfil the 1:8 ratio in late 2017, with full launch from 1st March 2018. In Wave 2 CCGs, the full launch of the increase ratio will be 1st March 2019. Existing evidence shows that IAPT is effective at improving health outcomes for some individuals, but evidence is more limited and mixed in relation to employment outcomes and the effect of the provision of EAs.
Objectives	The aim of this evaluation is to robustly determine the likely additional health and employment outcomes from additional employment advisers in IAPT services (in work, in work on sickness absence, and out of work). The results of the evaluation will inform the future design of integrated employment support in IAPT services and any further roll out decisions. There are two main strands to the evaluation. **Quantitative strand:** The quantitative strand aims to: • Understand reasons for participation and non-participation in EA in IAPT support • Evaluate the impact of receiving employment support on client health and work outcomes.

	• Contribute to understanding of the process of implementation by producing quantitative findings on what support clients have received and their experiences of support **Qualitative strand:** The qualitative evaluation aims to: • Understand how the policy was implemented by gathering feedback on client and staff experience in order to provide lessons learned from service delivery to inform the roll-out of wave 2 and design of any national roll-out • Assess the 1:8 EA to therapist ratio qualitatively to consider whether it is the most effective ratio, and to suggest improvements to the provision
Study Configuration	The quantitative survey strand will take place across *all* Wave 1 and Wave 2 CCGs. The qualitative strand will take place in eight case study Wave 1 CCGs only. Relevant providers for potential case study CCGs will be contacted in June 2018 and invited to participate in qualitative case studies.
Setting	IAPT services across 83 CCGs in England

Number of participants	**Quantitative strand: total c. 5,445 interviews with 4,245 individuals:**
	The quantitative strand will cover all 83 CCGs and comprises three client surveys:
	• Wave 1 (Time 1) – 3,045 clients who have received/are receiving therapy through IAPT in CCGs that have already seen an increase in EA ratio. This includes 1,845 clients that have taken up EA support and 1,200 clients that have not. Time 1 is intended to be approx. 4 months after starting therapy.
	
	• Wave 1 (Time 2) – follow-up interviews 7 months later with 1,200 of the original 1,845 Wave 1 clients that had taken up EA support (i.e. approx. 11 months after they started their treatment).
	
	• Wave 2 (Time 2) - interviews with 1,200 clients in Wave 2 areas *whose IAPT service did not include the increased EA ratio.* This survey is timed to ensure that respondents are comparable to those in Wave 1 Time 2 in that is approx. 11 months after starting treatment.
	
	Qualitative strand: total c. 224 interviews
	The qualitative strand will take place in eight CCGs over two time points.
	
	• Time 1:
	  • 24-32 Employment Adviser interviews
	  • 8 Senior Employment Adviser interviews

	• 16-24 clinician / therapist interviews • 4 regional lead interviews • 16 local partner interviews – Jobcentre Plus, Employability partners, other providers • 80 client interviews • Time 2 – longitudinal follow up interviews after 6-8 months with 60 of the same 80 clients interviewed at Time 1. If it is not possible conduct the full 60 interviews longitudinally, the sample will be boosted with new participants to reach 60.
Sample size estimate	The total sample sizes required to achieve the above participant numbers have been calculated based on previous experience of the CI and co-investigators in conducting other similar evaluation studies. Sample sizes for the survey assume a 10-20% response rate to an initial survey requiring roughly: • Wave 1 (Time 1) – 15-30,000 • Wave 2 (Time 2) – 6-12,000 For the qualitative element we propose sampling at a 5:1 ratio for staff, although this may not be possible where there are only a limited number of individuals within that job role. We suggest a 10:1 ratio for clients: • Employment Advisers – c. 200 • Senior Employment Advisers – c. 40 • Clinicians / therapists – c. 80 • Regional leads – 4 • Local partners – c. 120 • Clients – c. 800 plus potential sample boost.
Eligibility criteria	All clients who have had their IAPT assessment and begin IAPT therapy within the 83 pilot CCGs. No other specific factors are required as inclusion criteria, other than a lower age limit of 18.
Description of interventions	Quantitative: • Each survey will comprise a 20-minute telephone interview, carried out by interviewers from IFF, administered from the IFF telephone interviewing room. The interview would be at a time chosen by the participant. Qualitative: • At Time 1, 30-45-minute telephone interviews will be conducted with clients, while a 40-60-minute interview (EAs, therapists, employability partners) will be conducted face to face with all other qualitative participants, on a date/time of their choosing, onsite at the Trust. • Longitudinal (Time 2) client interviews will be conducted over the telephone and last up to 30

	minutes. Boost interviews at Time 2 will last 30-45 minutes and be conducted over the phone.
Duration of study	Fieldwork is due to start in July 2018, and finish in November 2019. Detail on each of the qualitative and quantitative strands are as follows: **Quantitative:** Time 1 interviews will occur between December 2018 and May 2019. The interviews will be carried out on a monthly, 'rolling' basis, new client contact details will be passed to IFF each month from October 2018 (where consent has been given). Each monthly cohort of clients will then be contacted (for opt out and then survey) 4-5 months after their IAPT start date which allows a sufficient period for most to have completed treatment. The survey window for each monthly cohort will be 4-6 weeks. If clients cannot be contacted or interviewed within that timeframe they will not be contacted or interviewed, as we want to ensure clients are consistently interviewed shortly after finishing treatment. Time 2 (both Wave 1 and Wave 2) interviews will occur between June 2019 and November 2019. Again, interviews will be carried out on a 'rolling' basis, so that we will allow a window of around 4-6 weeks to speak to each client. Our aim is to speak to clients approx. 11 months after they have started treatment (approx. 6-7 months after their Time 1 interview). **Qualitative:** All Time 1 qualitative fieldwork will all be carried out between July and September 2018 with staff, and November 2018 and January 2019 with clients. All Time 2 qualitative fieldwork will be carried out during and June and July 2019.
Outcome measures	The outcome measures used in the surveys include: • Clients' health (including EQ-5D and EQ-VAS) • Clients' general wellbeing (WHO-5, UCLA 3, ONS4) • Clients' confidence in managing their condition • Clients' current employment and benefits status • Clients' proximity to the labour market e.g. confidence in finding/staying in work, motivation to find (alternative work), ability to manage workload. These measures are self-reported.
Analysis	For the quantitative strand analysis comprises: • A full descriptive analysis of the data from each wave will be conducted comparing results for each

	of the key groups – employed, employed off sick, not-in-work (and where base sizes allow, by sub-groups such as demographics, work history etc). • Longitudinal analysis will enable progress on outcomes to be measured between Time 1 and Time 2 for Wave 1. • Statistical techniques (propensity score matching) will enable comparison of outcomes between Wave 1 and Wave 2 clients at Time 2 to identify net impact. The qualitative data will be analysed using the computer assisted analysis software Nvivo. The analysis will be structured according to key themes, to address the key evaluation questions including whether the policy is being implemented as intended, and unpick the mechanisms by which the outcomes identified have been achieved.

ABBREVIATIONS

BPSR	Bryson Purdon Social Research (Co-investigator)
CATI	Computer-Assisted Telephone Interviewing
CCG	Clinical Commissioning Group
CI	Chief Investigator
DHSC	Department of Health and Social Care
DWP	Department for Work and Pensions
EA	Employment Adviser
ESA	Employment and Support Allowance
HRA	Health Research Authority
HTTPS	Hypertext Transfer Protocol Secure
IAPT	Improving Access to Psychological Therapies
ICF	ICF Consulting (Co-investigator)
IFF	IFF Research (Chief investigator)
ISO 27001	ISO 27001 is an information security management system standard
JCP	Jobcentre Plus
NHS	National Health Service
PSM	Propensity Score Matching
ScHARR	School of Health and Related Research, University of Sheffield (Co-investigator)
SEA	Senior Employment Adviser
WHU	Work and Health Unit

STUDY BACKGROUND INFORMATION AND RATIONALE

BACKGROUND INFORMATION

In 2016, the Work and Health Unit (WHU) published Improving Lives: The Work Health and Disability Green Paper; at the heart of which is the government's ambition to get 1 million more disabled people into work over the next 10 years. This is one of the most significant inequalities in the UK today with less than 50% of disabled people are in employment, compared to 80% of non-disabled people. The gap has not changed significantly in recent years and now stands at 32 percentage points. Furthermore, only one in three disabled people with a mental health condition are in work, compared to one in eight non-disabled people[1].

Supporting individuals with mental health conditions, is central to achieving WHU goals to reduce health inequalities, increase employment and help to promote economic productivity and growth. People with mental health conditions make up a significant proportion of those with disabilities and health conditions overall.[i] Most recent figures suggest that between one in five and one in six of all working age people in England have at least one common mental health condition.[ii]

In addition, mental health conditions are an important cause of absence, both work-related and non-work-related, and of worklessness due to ill-health. Rates of mental health conditions are lower among people in full time employment (14 per cent), and higher among people out of work, particularly among people on out-of-work benefits (47 per cent).[iii] The latest data shows that around half of the overall Employment and Support Allowance caseload has a registered 'mental and behavioural disorder'.[iv]

The government has stated that improving the offer of support for people with mental health conditions is integral to their approach. The Five Year Forward View for Mental Health, published last year, sets out a series of actions to prevent mental ill health, improve services and reduce stigma. The government is investing in trials, proofs of concept and feasibility studies, to test ways of providing specialist support for people with common mental health conditions and ensure that they have access to the most effective health support when it is needed. There are three sub groups of focus within this approach:

- **Supporting those people with mental health conditions who are unemployed to move (back) into work**. The employment status of people with disabilities and health conditions can fluctuate but when someone is out of work due to a health condition and claims Employment and Support Allowance they can find it difficult to move back into work. Only around 3% of the ESA caseload stop receiving the benefit each month, and not all of these people return to work.[v]
- **Helping those in work to manage their condition and remain well**. Many (83%) of people who have a disability acquire it while they are in work[vi] but can be reluctant to request time off for therapy and so reduce their chances of getting appropriate help. Part

[1] Source: Labour Force Survey, April to June 2016 taken from the Work, Health and Disability Data pack.

of the problem lies with the stigma and discrimination attached to mental health conditions.[vii]

- **Helping those on sickness absence to make a successful return to work**. The longer a person is off sick, the more difficult it becomes for them to return to work and the less likely it is that they will return to work at all. Some 400,000 people leave the workforce after developing a disability or work-limiting condition each year.[viii] Timely diagnosis and intervention that could keep people in or help them to return to work is often unavailable, resulting in high numbers of people absent with relatively mild conditions and at risk of falling out of work.

Improving access to psychological therapies (IAPT)

The Green Paper [ix], and the recently published Command paper "*Improving Lives"*[x]*,* makes clear that timely access to support is a key factor in preventing mental health conditions from developing and worsening, helping more people to remain in work for longer and to improve their chances of getting back to work.

The Improving Access to Psychological Therapies (IAPT) programme began in 2008 and has transformed treatment of adult anxiety disorders and depression in England.

Since 2008, there has been a significant expansion in IAPT services and it has been successful in increasing access to NICE-approved treatments for common mental health conditions. However, there is considerable variation in services, with a waiting time of just over six days in the best performing areas and 124 days in the worst performing areas in 2014-15.[xi]

In addition, employment support has not always been prioritised for those receiving therapy. The provision of employment support has always been part of the IAPT offer with an expectation of one employment adviser for every eight therapists per service. However, 2015 data suggested that the operating ratio as closer to 1:50, with the gap in employment advice being plugged by Psychological Well-being Practitioners (PSPs).

As part of the 2015 Spending Review, the WHU secured investment to increase the number of employment advisers in IAPT services to the original 1:8 ratio, across 40-50% of Clinical Commissioning Groups in England. This investment complements the NHS England measure to increase access to psychological therapies and improve how these services join up with other services. By 2020/21, at least 25% of people (or 1.5 million) with common mental health conditions will access services each year.

RATIONALE

It is clear that health conditions have a significant impact on labour market participation and that work has an important role to play in tackling and improving health outcomes.[xii] Yet the evidence in relation to what and how interventions work, for whom and under which conditions is currently limited.

DWP has tested integrated employment and IAPT services in the past. In 2009 DWP introduced an Employment Adviser pilot programme in 11 areas in England (and subsequently expanded to comparable programmes in Scotland and Wales). The pilot aimed to test the proposition that provision of an integrated health and employment advice

service to employed IAPT clients would reduce the incidence of health-related job loss, increase the likelihood of an earlier return to work following health related absence, and reduce the number of people accessing out of work benefits.

The pilot evaluation assessed the impact of IAPT at an individual level and concluded that, with the advice of the EAs, clients had been able to address the problems they were facing, such that in many cases problems had been at least partially resolved. Clients also pointed to improvements in their overall work situation, such as their overall level of job satisfaction. However, in the absence of a counterfactual group, the evaluation was unable to definitively say whether these improvements might have occurred in any case or may have been the result of seeing an IAPT therapist.[xiii]

The expansion of Employment Advisers (EA) in IAPT offers the opportunity to conduct a large-scale evaluation of the effectiveness of additional employment support and the results will inform the future design of integrated employment support in IAPT services and any further roll out decisions.

STUDY PURPOSE AND AIMS

PURPOSE

Overall purpose	The purpose of this study is to determine the impact of additional employment advisers in IAPT (Improving Access to Psychological Therapies) services on client outcomes, as well to explore the delivery of integrated employment support in IAPT services. When IAPT services were introduced in 2008, a 1:8 ratio of EAs to IAPT therapists was expected to be embedded in delivery. However, there has been considerable differences between services in the actual ratio implemented (with some services operating at a ratio of 1:50). As part of the Spending Review 2015, extra funding was received to employ more EAs to bring the ratio up to the initial 1:8 figure that was proposed. The investment in additional EAs will be rolled out to 83 Clinical Commissioning Groups (CCGs) in two waves as part of a national pilot. Wave 1 will receive the additional EAs to fulfil the 1:8 ratio in March 2018, and Wave 2 will receive the increase in March 2019. The evaluation aims for the EA in IAPT pilot are: • To assess the impact of additional Employment Advisers (EA) in IAPT (the integrated model) on health and work outcomes and to suggest improvements to the provision • To understand how the policy was implemented by gathering feedback on client and staff experience to provide lessons learned from service delivery. The results of the evaluation will inform the future design of integrated employment support in IAPT services and any further roll out decisions.
Aims of quantitative strand	The quantitative strand of the evaluation aims to: • Understand reasons for participation and non-participation in EA in IAPT support. • Collect self-reported data on intermediate health and work outcomes for clients. • Contribute to understanding of implementation by exploring the support clients have received and their experiences of support. The quantitative survey uses a longitudinal approach. This allows for analysis of understanding and outcomes measurement within and between survey waves. The survey also aims to identify any differences in outcomes and experience for three key groups of clients: in work, in work on sickness absence, and out of work. Key questions include: • What is the client experience of receiving employment support? • Has employment support influenced clients' intermediate work outcomes and proximity to the labour market, e.g. attitudes to work and work-related behaviour? • What elements of employment support are considered to be more/less effective? • What reasons do clients give for not taking up employment support?

Aims of qualitative strand	The qualitative strand of the evaluation will explore how the policy was implemented and the pathways by which the policy was delivered; whether the policy is being implemented as intended and what, in practice, is felt to be working more or less well, for whom and why. The qualitative evaluation will comprise in-depth semi-structured interviews with IAPT clients and staff. Key questions include: • How effective was the training received by EAs and SEAs? • What was the client experience of EA in IAPT? • From an IAPT staff perspective, how has the intended 1:8 ratio been experienced? E.g. have new EAs freed up therapist capacity used to undertake employment support and advice? • What factors have helped/hindered delivery? Why? • How can the intervention be improved?

STUDY OVERVIEW

This study has been confirmed by the Health Research Authority (HRA) as a Service Evaluation, meaning no further ethical approval from the HRA or REC is required.

Of the 83 CCGs that have received funding for an increased number of EAs, half were assigned to "Wave 1" of the pilot, and so would receive the full increase in EA ratio from March 2018, and the other half assigned to "Wave 2", and so would receive the increase in EAs from March 2019.

The evaluation involves conducting both quantitative and qualitative research. It is being undertaken by a consortium of independent research organisations. These organisations are:

- IFF Research – chief investigator and responsible for the quantitative strand, as well as undertaking qualitative fieldwork
- ICF Consulting – responsible for the qualitative strand
- BPSR Social Research – responsible for statistical analysis of survey data to determine net impact.
- ScHARR – providing expert input to design, evaluation materials and analysis.

Quantitative evaluation

The quantitative strand involves conducting telephone survey interviews with clients that have experienced IAPT services. The interviews will explore clients' experience of the IAPT service and any EA support they have had, as well as information on their current employment and benefits, health and wellbeing measures, and demographics.

The quantitative strand comprises:

- Two surveys with clients in the Wave 1 pilot areas who interacted with IAPT services *after* the EA numbers were increased in their CCGs. The first Wave 1 survey (Time 1) covers both clients that did and did not take up EA support, the second (Time 2) focuses only on following up those that *did* take up EA support.
- One survey with IAPT clients in Wave 2 pilot areas who interacted with IAPT services at a similar time to the Wave 1 clients but *before* there was an increase in EA presence in the Wave 2 CCGs.

The quantitative strand is conducted over two time periods: "Time 1" and "Time 2" to enable longitudinal analysis of clients' experiences of support and any change in self-reported outcomes. These are described below:

- Time 1 interviews are intended to take place approx. 5 months after the client started their IAPT therapy. This assumes that, in the main, clients will be reaching the end of their treatment after a 3-month period.

- Time 2 interviews are intended to take place approx. 6 months after the first interview or approx.11 months after the client started treatment. This is to allow a sufficient time period to elapse for outcomes to materialise.

The timing and composition of the three surveys is therefore as follows:

- Wave 1 (Time 1) – 3,045 survey interviews with clients who have received/are receiving therapy in CCGs that have already seen an increase in EA ratio. This

includes 1,845 clients that have taken up EA support and 1,200 clients that have not. The survey will take place between December 2018 and May 2019.

- Wave 1 (Time 2) – longitudinal interviews with c.1,200 of the original 1,845 Wave 1 clients that had taken up EA support. This survey will take place between June 2019 and the end of November 2019.

- Wave 2 (Time 2) - interviews with 1,200 clients in Wave 2 areas whose IAPT service did not yet include the increased EA ratio. This survey will take place between will June 2019 and the end of November 2019. This survey is timed to ensure that respondents are comparable to those in Wave 1 Time 2 to assess any difference in outcomes between clients who went through IAPT *before* (Wave 2) and *after* (Wave 1) the increased EA ratio.

Interview sample sizes are designed to enable analysis of differences in outcomes and experience for three key groups of clients: in work, in work on sickness absence, and out of work.

Client contact details and sampling information for the quantitative strand will come direct from the IAPT providers. More information on what we are asking of IAPT providers in respect of client sample can be found in accompanying data transfer request documents.

Evaluation Data Transfer Request – Wave 1 and Wave 2.

Clients in both Waves 1 and 2 will be introduced to the evaluation by their IAPT therapist or EA and given a Client Information Sheet. For those in wave 1 and 2, who take up employment support, the information will be provided at the first appointment with an EA. For those who do not take up employment support, this will happen in the fourth therapy session.

Clients will be asked if they consent to their contact details and some basic demographic information being passed on to the Chief Investigator, IFF Research. Consent will be recorded on the IAPT data system. If clients consent to this, their contact details will be securely transferred to the CI by the provider's data controller. In the 8 qualitative case study CCG areas the sample will be split to create separate randomly-allocated samples for qualitative and quantitative strands. In non-case study areas, the full sample will be used for quantitative survey work.

Survey data

Before the Wave 1 Time 1 and Wave 2 Time 2 surveys, the CI will send a letter to all clients that have given their consent for contact. The letter will explain the purpose of the evaluation, and give the client a two-week window to 'opt out' of the quantitative survey via email, telephone or post. If the client opts out, they will not be contacted again.

For all surveys, clients that have not opted out will be called by an interviewer from IFF Research who will ask if they would like to take part a survey interview. If the client consents to this, the interviewer will arrange a time to call the client back and conduct a 20-minute telephone survey with them. If the client does not consent, they will not be contacted again.

At the end of the Wave 1 Time 1 survey, clients will be asked if they consent to being re-contacted, in order to conduct Wave 1 Time 2 interviews. If the client consents to this, they will be re-contacted approx. 7 months later by an interviewer from IFF Research.

Qualitative data

In case study areas, the CI will send a letter to clients that have given their consent for contact. The letter will explain the purpose of the evaluation, and give the client a two-week window to 'opt out' of the qualitative fieldwork via email, telephone or post. If the client opts out, they will not be contacted again.

Clients that have not opted out will be called by either an interviewer from IFF Research (two case study areas) or from co-investigator ICF (six case study areas) who will ask if they would like to take part in a telephone interview. If the client consents to this, the interviewer will arrange a time to call the client back and conduct a 30-45-minute telephone interview with them. If the client does not consent, they will not be contacted again.

At the end of the Wave 1 Time 1 qualitative interview, clients will be asked if they consent to being re-contacted, in order to conduct Wave 1 Time 2 telephone interviews. If the client consents to this, they will be re-contacted in approx. 7 months.

Qualitative evaluation

The qualitative strand involves a combination of in-depth face to face and telephone interviews with IAPT clients, EAs, therapists, Employability Partners and CCG leads.

The qualitative strand will be used to explore how the policy is implemented and the pathways by which the policy is delivered; how clients came to use the service, what support they have received, and whether they have seen any benefits or impacts from the support they received.

The qualitative strand involves eight 'case study' CCG areas, two per region, to concentrate resources and establish clear links between experiences of provision and outcomes. Potential case study areas will be selected by WHU, co-investigator (ICF Consulting) and the CI, on the basis of where activity is most advanced while ensuring a spread of CCGs by socio-economic characteristics and by urban/rural location. Providers in relevant potential case study CCGs will be contacted in June 2018, invited to participate, and the study aims and requirements explained.

The co-investigator (ICF Consulting) will be responsible for fieldwork in six CCG areas and IFF, the CI, will be responsible for two areas.

The timing and composition of the qualitative strand is as follows:

- Time 1 – July 2018 to January 2019:
    - 24-32 Employment Adviser interviews
    - 8 Senior Employment Adviser interviews
    - 16-24 clinician / therapist interviews
    - 4 regional lead interviews
    - 16 local partner interviews – Jobcentre Plus, Employability partners, other providers
    - 80 client interviews - predominantly by telephone (option of face to face given to clients)

- Time 2 – June to July 2019.

- Longitudinal telephone follow up after 6-8 months with 60 of the same 80 clients interviewed at Time 1.
- If it is not possible conduct the full 60 interviews longitudinally, the sample will be boosted with new participants to reach 60).

Prior to the Time 1 fieldwork (and for any boost sample required at Time 2), IFF will send opt-out letters to all clients in qualitative sample in the 8 case study areas. The letter will explain the purpose of the evaluation, and give the client details of how to opt out should they not want to take part in the evaluation via email, telephone or post (a postage paid label will be provided).

In six of the eight case study areas, IFF will securely transfer the qualitative sample of client that have not opted out, to the co-investigator ICF. They will continue to securely transfer details of any further opt outs that come in after the initial transfer.

All clients that do not opt out will be contacted by an interviewer from ICF (in six case study areas) or IFF (in two case study areas) to arrange a time to meet the client and conduct a 30-45 minute interview with them (if the client does not consent, they will not be contacted again).

At the end of the Time 1 interview, clients will be asked if they consent to being re-contacted in 6-8 months, in order to conduct Time 2 interviews. If the client consents to this, they will be re-contacted 6-8 months later by an interviewer from ICF or IFF, at which point they can choose whether or not take part in another interview.

STUDY MANAGEMENT

The Chief Investigator IFF Research has overall responsibility for the study and shall oversee all study management.

A data controller at each relevant IAPT provider will be responsible for selecting all clients on the database who gave their consent for their details to be passed on, and transferring their contact details securely to the CI, IFF Research.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

There are several stages to recruiting clients, which are set out below. There is some overlap with the 'consent' section (below this section), as most stages of recruitment involves gaining client consent. For detailed information about consent procedures and statements, please see the consent section.

The recruitment processes vary slightly depending on whether the CCG is one of the eight case study areas (and therefore clients will be contacted about either qualitative or quantitative research) or a non-case study CCG area (quantitative survey only)

Non-case study CCG areas – quantitative survey research only

There are three main steps of recruitment in non-case study CCG areas. These are set out in the diagram below with further detail in the accompanying text, with accompanying documents found in Appendix A.

Please note all information about consent is contained in a later section.

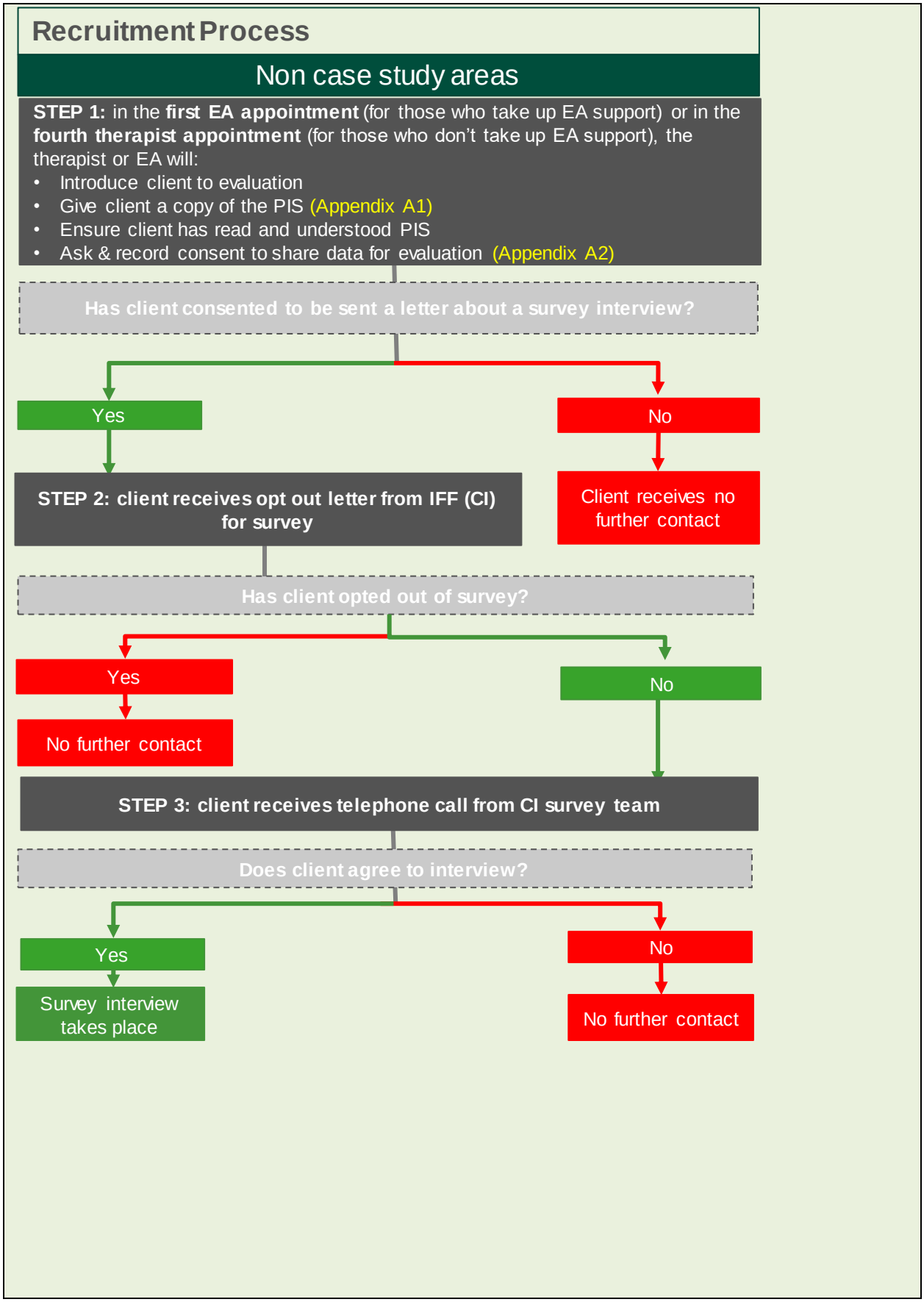
Step 1: Clients will be introduced to the evaluation either by their EA in their first EA appointment (for those who take up EA support in each wave), or by their therapist in their fourth therapy session (for those who do not take up EA support). The EA / therapist will explain the purpose of the evaluation, with the aid of a Client Information Sheet. The Client Information sheet used in non-case study areas will describe the quantitative survey strand **(Appendix A1)**. The EA / therapist will establish whether the client consents to have their details securely transferred to IFF (CI) and record this on the IAPT system (**Appendix A2**).

The process for transferring client details for survey will differ between Wave 1 and Wave 2 areas. In Wave 1 areas, between October 2018 and March 2019, client details will be transferred to IFF (CI) on a monthly basis by the data controller at the IAPT provider. In Wave 2, there will be two data transfers of client details:

- For clients starting treatment between 1st July and 30th September 2018, the data transfer date will be January 2018;
- For clients starting treatment between 1st October and 31st January 2018, the data transfer date will be March 2019.

Step 2: An "information and opt-out letter" will be sent to each client that consented for their details to be securely transferred to IFF. The letter will provide details of how to opt out of the evaluation and explain that, if they do not opt out, then an interviewer from IFF will call the client to ask if they would like to participate in the quantitative survey.

Step 3: An IFF interviewer will call all clients that did not opt out after receiving the letter. The interviewer will ask if the client would like to participate in a survey interview and if the client agrees, the interviewer will arrange a convenient time to conduct the interview.


Recruitment Process
Non case study areas
STEP 1: in the first EA appointment (for those who take up EA support) or in the fourth therapist appointment (for those who don't take up EA support), the therapist or EA will:
• Introduce client to evaluation
• Give client a copy of the PIS (Appendix A1)
• Ensure client has read and understood PIS
• Ask & record consent to share data for evaluation (Appendix A2)
Has client consented to be sent a letter about a survey interview?
Yes
No
STEP 2: client receives opt out letter from IFF (CI) for survey
Client receives no further contact
Has client opted out of survey?
Yes
No
No further contact
STEP 3: client receives telephone call from CI survey team
Does client agree to interview?
Yes
No
Survey interview takes place
No further contact

Case study areas: qualitative and quantitative evaluation

The recruitment process in case study areas is set out in the diagram below with further detail in the accompanying text, and accompanying documents found in Appendix B.

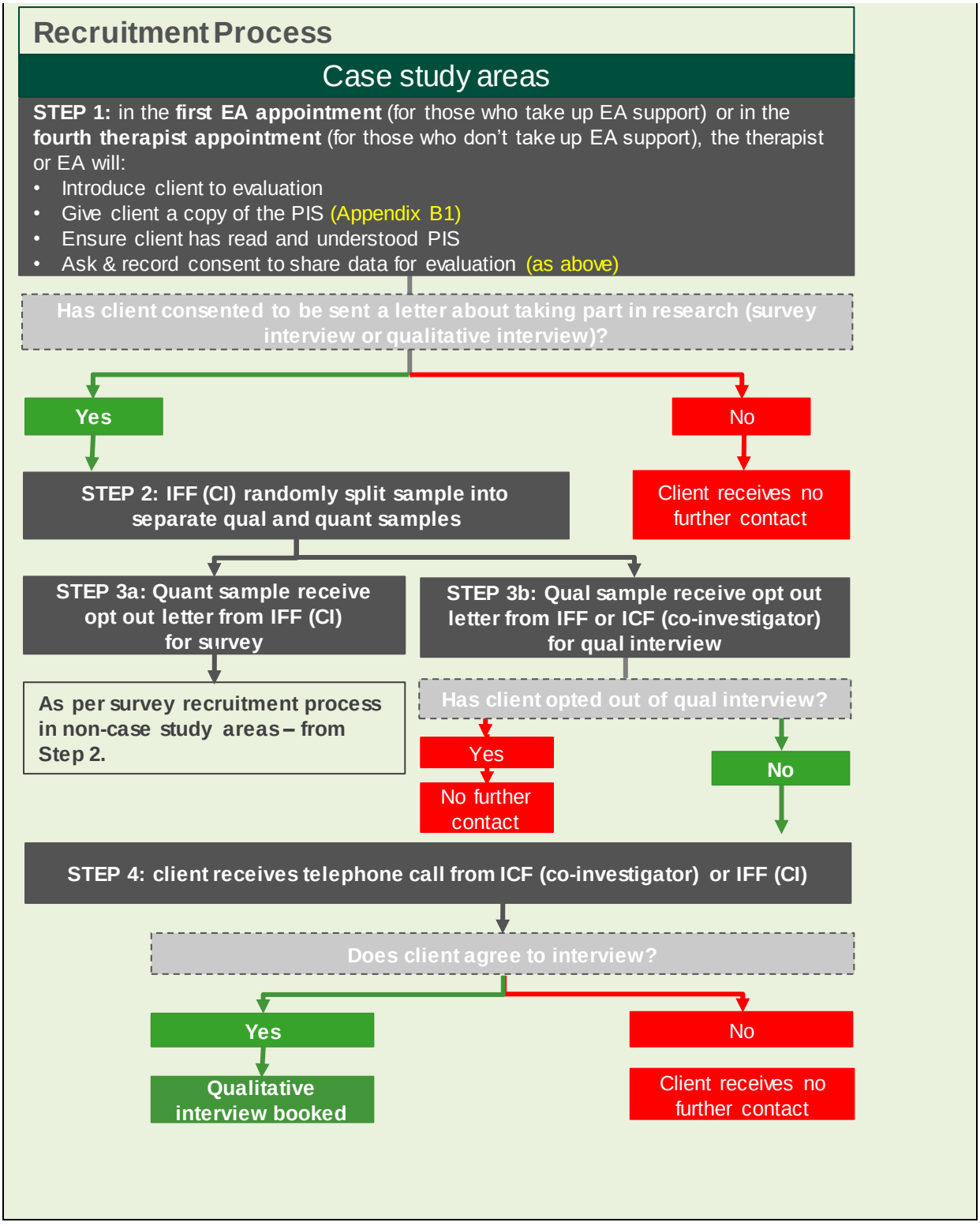
Please note all information about consent is contained in a later section.

Step 1: Step 1 is identical to that described above for the non-case study areas. The Client Information Sheet **(Appendix B1)** describes both the quantitative and the qualitative strands, and explains that consenting clients will be randomly allocated to one strand or the other. The process for recording client consent and transferring client details to IFF (CI) is as described above.

Step 2: Once details of consenting clients have been received by IFF, they will be randomly allocated to either the qualitative or the quantitative strand of the research (sample size requirements are discussed elsewhere in this document).

Step 3: Those clients in the quantitative sample will receive the 'information and opt out' letter from IFF as described above. Those clients in the qualitative sample will be sent an 'information and opt-out' letter about the qualitative research. The opt out process for both strands will be managed by IFF (CI).

Step 4: An IFF or ICF researcher (depending on the case study CCG area) will call those clients that did not opt out after receiving the letter. The researcher will ask if the client is happy to take part in a qualitative interview.


Recruitment Process
Case study areas
STEP 1: in the first EA appointment (for those who take up EA support) or in the fourth therapist appointment (for those who don't take up EA support), the therapist or EA will:
• Introduce client to evaluation
• Give client a copy of the PIS (Appendix B1)
• Ensure client has read and understood PIS
• Ask & record consent to share data for evaluation (as above)
Has client consented to be sent a letter about taking part in research (survey interview or qualitative interview)?
Yes
No
Client receives no further contact
STEP 2: IFF (CI) randomly split sample into separate qual and quant samples
STEP 3a: Quant sample receive opt out letter from IFF (CI) for survey
STEP 3b: Qual sample receive opt out letter from IFF or ICF (co-investigator) for qual interview
As per survey recruitment process in non-case study areas – from Step 2.
Has client opted out of qual interview?
Yes
No further contact
No
STEP 4: client receives telephone call from ICF (co-investigator) or IFF (CI)
Does client agree to interview?
Yes
Qualitative interview booked
No
Client receives no further contact

Participant Withdrawal

Quantitative and qualitative evaluation

Participants may be withdrawn from the study at their own request. The participants will be made aware that this will not affect their future care or relationship with the IAPT Provider, WHU, DWP, DHSC, JCP or the NHS.

They can withdraw at any point, but the recruitment points outlined above are key opportunities for participants to withdraw through not consenting to participate.

Participants will be made aware (via the Client Information Sheets and opt out letters) that they can choose to withdraw from participation at any point during the study. This can be done by the client notifying IFF (CI) and/or ICF (co-investigator) – either directly or via their IAPT provider. It is the client's choice whether any personal information or data they have provided so far is erased. If the client chooses to have their data erased, their data will be erased by IFF Research and/or ICF. Clients will also be made aware (via the Client Information Sheets and opt out letters) that they have a right to access data held on them, including their personal data and any survey data / recordings. As with withdrawal, this can be done by the client notifying IFF (CI) and/or ICF (co-investigator) – either directly or via their IAPT provider.

If the client changes their mind about being involved after they have taken part in survey or qualitative interviews, they can ask IFF Research (CI), or ICF (co-investigator) – either directly or via their IAPT provider - to erase their data, and it will not be included within the analysis, or reported on. The Client Information sheet and opt out letters will stipulate the timescales for requesting removal from analysis.

Gaining informed consent

We will ensure that any consent given by the participant is informed – i.e. the participant understands what they are consenting to, and why, before they either give or refuse consent.

The initial step in the consent process is almost identical in both the quantitative and the qualitative strand and begins either **in the first EA appointment** (for those who take up EA support) or **in the fourth therapist appointment** (for those who don't take up EA support).

In the relevant appointment, the EA or therapist will provide clients with an information sheet about the evaluation. In CCG areas where only the quantitative survey will be carried out (non-case study CCGs), the information sheet will only mention the quantitative element (**see Appendix A1**). In the 8 CCG areas that will also experience the qualitative strand (case study areas), the information sheet will discuss both elements of the research, and explain that consenting clients will be randomly allocated to one type of research or the other (**see Appendix B1**).

Regardless of the information sheet used, the EA or therapist will make clear that the evaluation is entirely voluntary, that participation or non-participation will have no impact on the care they receive, and that they can withdraw at any time.

The EA / therapist will then read out a series of consent statements to the client, to ask clients if they consent to sharing the following information with IFF Research (CI): their name, address, phone number, employment status, whether they are receiving any employment support within IAPT.

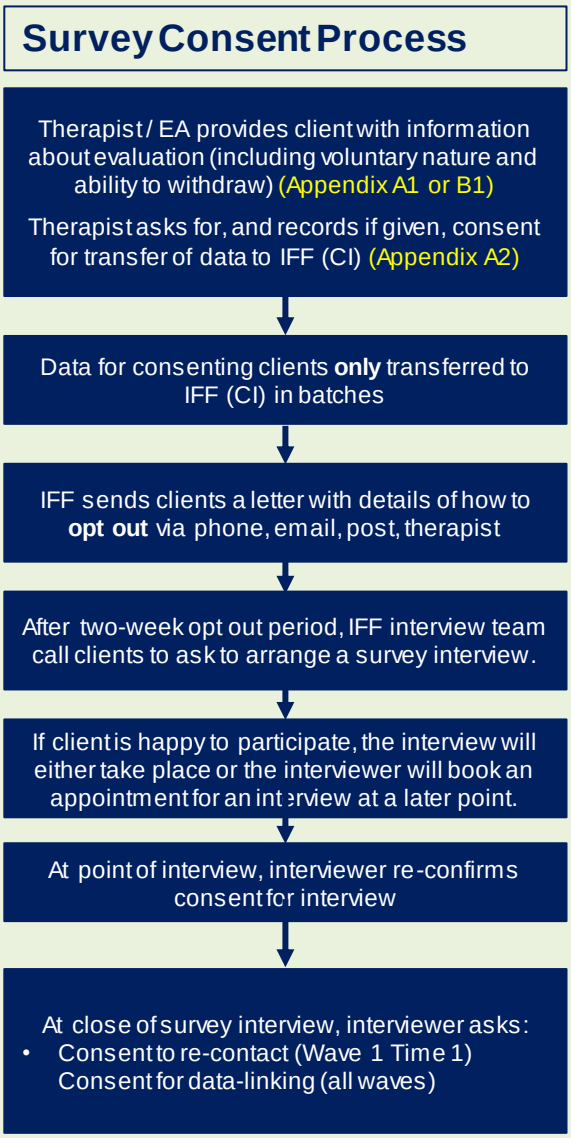
Overall consent to share all these details (or, conversely, none of them) will be recorded digitally, via the IAPT data system (**Appendix A2**).
From here, the qualitative and quantitative consent processes diverge slightly. Client records will be randomly allocated by IFF Research (CI) either to the qualitative or quantitative strand of the research.

The consent processes for the qualitative and quantitative strands are set out in the diagrams below. The processes are similar, but there are small differences, so they are discussed separately.

Please note that the consent process operates alongside the recruitment process outlined above so some of the documentation has the dual purpose of both recruitment and consent.

Quantitative strand

The relevant accompanying documents for gaining consent for the quantitative strand can be found in Appendix A.



The opt out letter

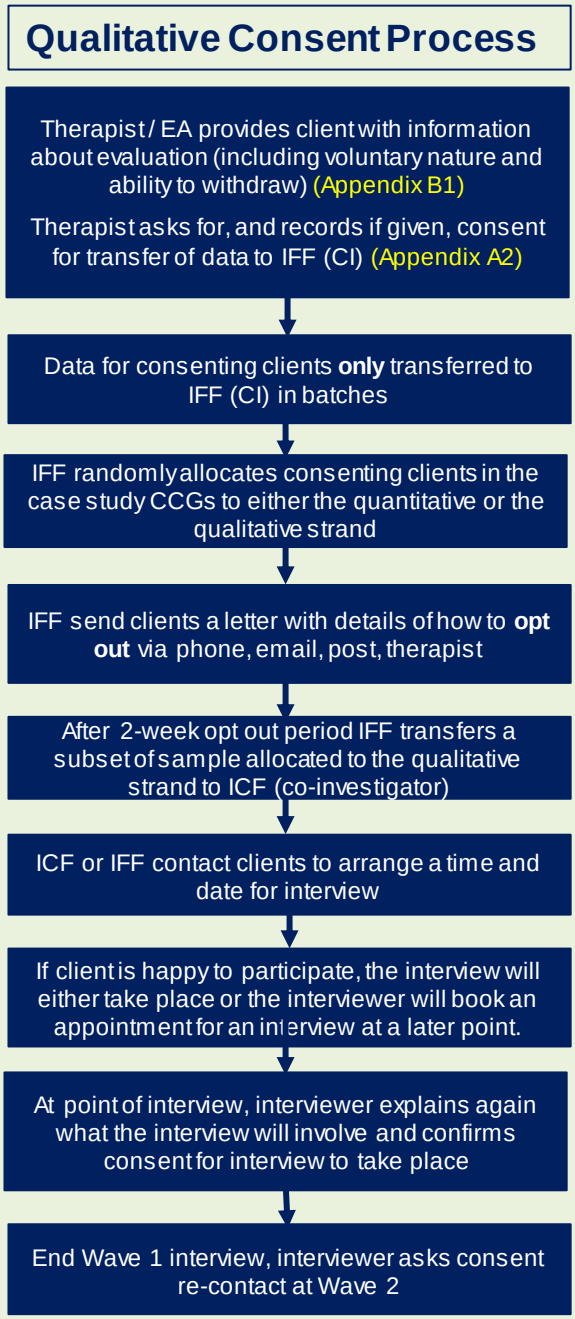
Once data from all consenting clients has been transferred to IFF Research (CI), IFF Research will send an opt out letter to those allocated to the quantitative evaluation strand.

The letter provides more detail about the survey. The letter explains that the client can opt out of the research over the subsequent 2 weeks by phone, email, post or via their therapist and if they choose to do this, then will not be contacted again about the evaluation.

The letter will explain that if they do not opt out, then an interviewer from IFF will call the client to ask if they would like to participate in the quantitative survey. The letter will also give contact details of researchers at IFF Research and WHU, so the client can call or email with any questions.

	Telephone recruitment If the client does *not* opt out following receipt of the letter, they will be contacted by a member of the IFF interviewing team by telephone. The interviewer will follow a script which reiterates information about the study, explains again what is involved in taking part in a survey interview, and establishes whether the client is able to give informed consent. Establishing whether individuals can give informed consent is critical and particularly so for individuals with mental health conditions. Interviewers will devote good time to explaining the background and what participation will involve and will be instructed that if concerns exist then they should err on the side of caution and stop recruitment. In some circumstances, if they are concerned about comprehension, interviewers will ask the respondent just to repeat back their understanding of what the Service Evaluation will involve so that they can check comprehension. If the client gives their consent to take part in an interview, the interviewer and the client will agree a mutually convenient time for the interview to take place. All interviews will be conducted with humanity and sensitivity. This means that: • Interviews are conducted at the respondent's pace and can take place over more than one session; • The rationale for personal questions is explained; • Interviewers will stop if the respondent is becoming distressed by the process (and offer to contact a friend/relative if appropriate); Should interviewers be concerned about a respondent's welfare then they will escalate the issue to the IFF team (who will discuss with the WHU if appropriate). If the client is unable to take part in the survey interview straight away the interviewer will book an appointment time to call back. When this call back occurs, the interviewer will repeat the same script to provide another opportunity to give informed consent. **Additional consents** If the client has completed a Wave 1 Time 1 survey interview they will be asked at the very end whether they consent to taking part in the follow up Time 2 interview. Clients who complete any of the three surveys are asked at the end whether they give their consent for: • Their survey responses to be linked to IAPT data. • Re-contact to clarify any information gathered during the survey (this is standard survey practice).
Qualitative strand	The consent process for the qualitative interviews is set out in the diagram below, with further detail in the accompanying text. The relevant accompanying documents can be found in Appendix B, please note that the consent process operates alongside the recruitment process outlined

above so some of the documentation has the dual purpose of both recruitment and consent.



The opt out letter

IFF will send an opt out letter to all those allocated to the qualitative strand. The letter provides more detail about the qualitative research. The letter explains that the client can opt out of the research over the subsequent 2 weeks by phone, email, post or via their therapist and if they choose to do this, then will not be contacted again about the research.

The letter will explain that if they do not opt out, then an interviewer from IFF or ICF will call the client to ask if they would like to participate in a qualitative interview. The letter will also give contact details of researchers at IFF / ICF Research and WHU, so the client can call or

	email with any questions. The letter also contains information of a £15 voucher as a thank you for participation. **Telephone recruitment** Clients that have not opted out of the qualitative strand in the 2 weeks after receiving the letter and who are in the six case study areas lead by ICF (co-investigator) will be securely transferred from IFF to ICF. Clients that have not opted out across all eight case study areas will be contacted by a member of the ICF or IFF (depending on the case study area) interviewing team by telephone. The interviewer will follow a script which reiterates information about the study, explaining again what is involved in taking part in the research. This is an opportunity to confirm that the client understands what is involved and is able to give informed consent (see quantitative consent section above for further explanation of informed consent). **Interview introduction** Given that the interview may take place days or weeks after recruitment, it is important to re-establish consent to participate. At the start of the qualitative interview the interviewer will confirm that the client is still happy to take part and formally record that the individual has understood this by completing the written consent form. Where interviews are conducted over the phone, this will be recorded orally and tape-recorded as evidence. **Additional consents** If the client completes a Time 1 interview they will be asked at the very end whether they consent to taking part in the follow up Time 2 interview.

Eligibility criteria

Quantitative strand	**Clients** are eligible if they: • Are using IAPT services within the 83 identified CCGs • Give consent to take part in the evaluation • Are aged over 18 (no upper age limit)
Qualitative strand	**Clients** are eligible to take part in the evaluation if they: • Are using IAPT services within the 8 case study CCGs • Give informed consent to take part in the evaluation • Have used the services of an EA during their contact with the IAPT service • Are aged over 18 (no upper age limit) **Therapists, EAs and Employability Partners** are eligible to take part in the evaluation if they: • Are working as an IAPT therapist, EA or Employability Partner in one of the 8 case study CCGs • Give consent to take part in the evaluation

ANALYSIS

Quantitative analysis	For the quantitative strand analysis comprises: • A full descriptive analysis of the data from each wave will be conducted comparing results for each of the key groups – employed, employed off sick, not-in-work (and where base sizes allow, by sub-groups such as demographics, work history etc. • Longitudinal analysis will enable progress on outcomes to be measured between Time 1 and Time 2 for Wave 1. • Statistical techniques (propensity score matching) will enable comparison of outcomes between Wave 1 and Wave 2 clients at Time 2 to identify net impact. Cross-sectional and longitudinal analysis will be undertaken by IFF (CI), with statistical matching and impact assessment will be undertaken by BPSR (co-investigator). The key comparisons to be made within the quantitative analysis: • Comparison between 'Time 1' clients and 'Time 2' clients in Wave 1 areas • Comparison between clients that actually used EA support, and those that did not • Comparison between outcomes within the key three subgroups: o Individuals in employment who are at work o Individuals in employment who are off work sick o Individuals who are not in work Matching variables collected within the survey will form the basis for propensity score matching (PSM) to identify a 'matched comparison group' amongst Wave 2 Time 2 clients for the Wave 1 Time 2 clients. A comparison will then be made between the matched Wave 1 and Wave 2 Time 2 groups on key client outcomes to determine to measure the impact of employment support on those who take it up (the 'treated'). The outcome measures used in the surveys include: • Clients' health (including EQ-5D and EQ-VAS) • Clients' general wellbeing (WHO-5, UCLA 3, ONS4) • Clients' confidence in managing their condition • Clients' current employment and benefits status • Clients' proximity to the labour market e.g. confidence in finding/staying in work, motivation to find (alternative work), ability to manage workload. These measures are self-reported.
Qualitative analysis	The qualitative interview data will be analysed using the computer-assisted analysis software NVivo. The analysis will be structured to address the key evaluation questions including whether the policy is being implemented as intended, and unpick the mechanisms by which the outcomes identified have been achieved. The analytical approach comprises five steps:

	• **Interview transcription** – the recordings of each interview will be anonymised, and transcribed prior to analysis. • **Development of coding framework** – the coding framework will be piloted using two interviews from each respondent group, and amended as required (and iteratively throughout the coding process). • **Development of independent attributes** – once transcripts are uploaded onto NVivo they will be classified according to a set of attributes/independent variables, which can be cross-referenced to the coded analytical statements. • **Coding the interview data** – each interviewer will each code their own interviews, with the first two interviews from each respondent type being reviewed by the project manager to ensure consistency. • **Producing reports and queries –** we will produce outputs by code, cut by interview source and attribute, to provide insights into how different experiences and outcomes vary by independent factors.

Sample size and justification

Quantitative evaluation

Interview sample sizes are designed to enable analysis of differences in outcomes and experience for three key groups of clients: in work, in work on sickness absence, and out of work. The evaluation must ensure that the analysis can pick up any differences between key groups of clients:

- Clients receiving employment support, and those not receiving employment support, and *within that:*
- Clients in three key subgroups:
    - Employed – in work
    - Employed – off sick
    - Unemployed

A common starting point for designing sample structures for social surveys is to try to ensure an achieved sample of around 400 interviews for each core sub-group of interest. This is on the basis that this is the sample size required to ensure a maximum standard error of +/-5% (for findings at the 50% mark) which is generally considered to be a good level of robustness for surveys of this type.

However, clients that received EA support at Time 1, will be *re-contacted* at Time 2. Therefore, the sample size amongst these clients has been increased from 400 in each cell, to 615 (as shown in the table below) to allow for attrition between the two time periods. This attrition could occur for several reasons:

- We will need to ask permission to re-contact at the end of each stage of interviewing and some will decline. We would estimate that the proportion agreeing to re-contact will be around 90-95% at each stage.
- A proportion of telephone numbers that worked 6 months ago are likely to be incorrect/unobtainable at the follow-up stages (c.15-20%).
- The nature of individuals' health conditions will mean that some are unable to participate at follow-up stages for health reasons.

Therefore, to allow for robust analysis at both waves, the total number of interview quantitative interview completes should be 3,045 at Time 1, and 1,200 at Time 2 (both Wave 1 and Wave 2), therefore 5,445 in total.

	"Time 1" (3-4 months after starting therapy) – Wave 1 only	"Time 2" (11 months after starting therapy) – Wave 1 and Wave 2
Individuals receiving employment support		
Employed – in work	615	800
Employed – off sick	615	800
Unemployed	615	800
Individuals not receiving employment support		
Employed – in work	400	
Employed – off sick	400	
Unemployed	400	
Total	3045	2400

To calculate the total sample size required, the likely rate of customer consent and response to the survey, and proportion of customers taking up employment support must be considered. These are currently unknowns so we have to work on best estimates at this point. We have calculated the requisite sample size to achieve the interview numbers outlined above as follows:

Numbers	Breakdown
567,106	Annual number of people who complete IAPT treatment
(÷12) = 47,258	Monthly number of people who complete IAPT treatment
(Trial is across 40% of CCGs) = 18,903	No. of people per CCG in trial who complete IAPT treatment each month
(50% of CCGs in Wave 1) = 9,451	No. of people in Wave 1 of trial who complete treatment each month
(50% of CCGS in Wave 2) = 9,451	No. of people in Wave 2 of trial who complete treatment each month
(50%) = 4,725	Wave 1 - Assumption that approx. 50% of clients consent to pass their details on and be contacted by IFF Research to be invited to take part in either a survey or interview (per month)
(50%) = 4,725	Wave 2 - Assumption that approx. 50% of clients consent to pass their details on and be contacted by IFF Research to be invited to take part in a survey (per month)
(10%) = 472	Wave 1 – Assumption that approx. 1 in 10 people actually complete the survey/interview after being contacted, invited to take part, opt-out period completed, and survey/interview scheduled at convenient time (per month)
(10%) = 472	Wave 2 – Assumption that approx. 1 in 10 people actually complete the survey/interview after being contacted, invited to take part, opt-out period completed, and survey scheduled at convenient time (per month)

With a six-month sampling window, we therefore estimate a total pool of **5,664 people** who are likely to complete either a survey/interview. In total, **we require 4,325 people** to complete either a survey or interview (3,045 W1T1 survey, 1,200 W2T2, 80 interviews).

Sampling is further complicated by the fact that, to permit the desired analysis, respondents need to be broken down by employment status and take up of employment support. Please note that early management information shows approx. 8% take up of employment support in Wave 1.

These are conservative assumptions and we expect employment support take up to build. However, they demonstrate that we need to ask all providers to collect data for all clients. Sampling numbers will be monitored monthly, and the sample window can be shortened if numbers are reached earlier. However, if the numbers are not achieved by 6 months, the window will need to be extended.

Qualitative evaluation

The qualitative strand will be focussed in eight CCG areas, two per region, to concentrate resources and establish clear links between experiences of provision and outcomes. ICF will be responsible for fieldwork in eight CCG areas and IFF in two, with a single consultant being allocated to each CCG for the Time 1 and 2 fieldwork. Additional interviews with regional CCG leads will triangulate the findings with wider regional practice; and with Jobcentre Plus and other employment services explore collaborative working.

Qualitative data is not designed to be representative of the population in question, but rather to gain detailed insight into individual experiences. Therefore, there are not 'minimum' numbers of interviews to be gained in each cell.

The qualitative element of the evaluation will focus on the nature and effectiveness of the enhanced provision from staff and client perspectives, to provide key insights to inform preparations for Wave 2 of the programme. The numbers proposed are based on the volume required to gather a holistic range of perspectives and experience describe a 'case' in sufficient depth and quality.

We propose sampling at a 5:1 ratio for staff, although this may not be possible where there are only a limited number of individuals within that job role. We suggest a 10:1 ratio for clients.

Interviewee type	Total interviews, all 8 CCGs	Sample required
EA	24-32	100
SEA	8	40
Therapists/clinicians	16-24	120
Clients	80	800 plus any boost required for Time 2
Regional leads	4	4
Local partners – Jobcentre Plus and other providers	16	80

ETHICAL AND REGULATORY ASPECTS

Quantitative and qualitative evaluation

Although not expected, if participants feel any psychological harm or disturbance when completing the survey or qualitative interviews, they will be provided with contact details of the CI or the co-investigator, to discuss these further. The CI or co-investigator will also provide them with information about other support resources, such as the Samaritans.

If participants disclose that they are at risk from harm, either self-harm or harm from another individual, the following steps will be taken:

1. Interviewer will seek permission to contact someone on their behalf, providing reassurance that their information will remain confidential unless they give you permission to pass the disclosure on.

2. If the participant consents to contact with a third party on their behalf:

    - Interviewer will confirm with the participant that their nominated individual(s) will be contacted and the context of how we will make disclosure will be explained: that the participant was taking part in a survey which includes questions on wellbeing, and has asked us to contact them, because during the interview they let us know that <details of disclosure>

    - All contact details for the nominated individual(s) will be collected and logged: full name, organisation, contact phone number(s).

    - The nominated individual will be contacted as soon as possible.

3. If the participant does not consent to contact with a third party on their behalf:

    - It will be confirmed that without their permission no information will be passed on, and their answers will remain confidential.

    - Contact details for support organisations will be offered (e.g. the Samaritans).

ETHICS COMMITTEE AND REGULATORY APPROVALS

Quantitative and qualitative evaluation

The study has been confirmed by the HRA as a “service evaluation” therefore no further ethical approval by the HRA or REC is required.

RECORDS

Client identity

Quantitative and qualitative evaluation

Each participant will be assigned a study identity code number, for use on the CI's electronic database and SPSS files. In addition, the names and addresses of participants (which are collected by the IAPT system as a matter of course and securely sent to the CI if the client gives consent for this) will be recorded and may be used to identify participants alongside the coding system.

Treatment of source documents

Quantitative evaluation

There will be no source documents associated with the quantitative strand

Quantitative and qualitative evaluation

Source documents – notes from qualitative interviews shall be filed securely in locked cabinets at the investigators' sites. They will then be scanned, and electronic copies kept in secure servers and hard copies destroyed.

Record of interviews

Quantitative and qualitative evaluation

All quantitative and qualitative interviews carried out will be audio recorded, and these recordings will be stored securely at the investigators' sites on secure servers.

DATA TRANSFER AND STORAGE

Client sample data transfer

Client sample data would be encrypted to AES-256 standard and transferred from IAPT providers to IFF Research via IFF's (CI) secure file exchange website.

This site is hosted in-house on IFF's own encrypted server. Data transfer can only occur when using an approved registered account and data must be encrypted to AES-256 compliance and password protected. Data separation is guaranteed; an approved registered account will only ever show the data relevant to the organisation or individual. The end user is always in control of their account credentials which are not known to anyone else, including IFF Research.

Only the data that clients had consented to be transferred will be uploaded – the consent for data transfer can be found at **Appendix A2.**

After the file is downloaded from the secure filesharing website, the sample file is saved to a folder on IFF's secure network. Sample data will have ownership assigned to the CI as the data owner. Initially only the 'owner' and IT administrative staff are explicitly granted access to the client data which is stored on a secure area of our network. All other access is granted on an as needs basis and revoked when it is no longer required. This access is logged on our data asset register.

For the qualitative evaluation, in six case study areas IFF will transfer details for those clients that have not opted out of participation, and securely transfer their details to ICF (co-investigator). The transfer will take place via PGP encryption software. PGP is a hybrid cryptosystem. PGP creates a session key, which is a one-time-only secret key. Once the data is encrypted, the session key is then encrypted to the recipient's public key. This public key-encrypted session key is transmitted along with the ciphertext to the recipient. Prior to any transfer a public key exchange must take place and data must not be transferred unless both parties have agreed and are present for the transfer to take place.

As part of IFF's ISO 27001 requirements all sub-contractors sign our Data Handling and Non-Disclosure Agreements.

At ICF all sensitive electronic data will be held on a secure server, with access to it being restricted to members of specific project teams. No sensitive information will be stored on hard drives and other portable media.

Quantitative survey data collection and storage

All telephone survey data collected through IFF's CATI system will be held on IFF's data collection platform, IBM's SPSS Dimensions. Dimensions is hosted on IFF's internal web server, access to any activity is limited exclusively to Certificate Authority-issued Secure Sockets Layer (SSL) certificate HTTPS connections. This ensures all data entry in transit is encrypted to the highest contemporary standards. Compliance with latest security standards is reviewed and tested monthly, and upgraded as needed.

Data entered into the Dimensions system is transferred to our secure storage area which fully encrypted at hardware level. Full hard disk encryption is employed, secured with UEFI secure boot, TPM 2.0 key protection and Microsoft Server 2012 R2 BitLocker. Daily backups are taken for business continuity and data integrity. The backed-up data is subject to segregated backup processes and the backups are fully encrypted and accessible by IT administrative staff only.

The data from Dimensions is downloaded into an anonymised SPSS file and set of tabulations are created, in line with a specification set out by the evaluation team. These outputs are stored on IFF's network which can only be accessed by users with secure login credentials.

Qualitative data collection and storage

All qualitative interviews will be recorded using encrypted Digital Voice Recorders (DVRs). Any other data will be collected on password protected encrypted laptops along with password protected encrypted USB data storage devices (recorders). Personal data will not be downloaded to any portable device.

Recordings and electronic notes are returned to IFF/ICF offices either in person or by uploading them via an encrypted laptop, using IFF's secure file-sharing site. All recordings and transcripts of recordings are stored in an encrypted, restricted access folder on IFF/ICF networks.

Any hard copy data received or created as part of our work:

- Is stored in locked cabinets on IFF/ICF premises;
- Is not taken away from premises unless absolutely necessary; and
- Is destroyed six months following completion of the assignment to which it relates by use of cross-cut shredders, and disposed of as 'confidential waste'.

DATA PROTECTION

Quantitative and qualitative evaluation

As Chief Investigator IFF Research takes the issue of data security extremely seriously and takes all reasonable steps to ensure the safety and confidentiality of respondents' records and of management/ administrative data provided by our clients and of survey data collected. IFF holds ISO/IEC 27001:2005 accreditation (the international standard for information security).

The data security accreditation is reviewed every 3 years by external auditors (BSI). These external auditors also conduct an assessment on all aspects of our data security approach (assessing these against the ISO standards) every 6 months, while external information security specialists also conduct an informal review every 6 months – meaning that our whole approach – both theory and implementation – is subject to a feedback and improvement loop on a six-monthly cycle. This approach is supported by regular management review meetings.

As part of IFF's ISO 27001 requirements all sub-contractors sign our Data Handling and Non-Disclosure Agreements.

DATA DESTRUCTION

After 6 months of inactivity, all secure data files will be archived (transferred onto a separate secure area). The data is then destroyed seven years after the evaluation is finished.

Where data is to be destroyed at IFF it will be deleted securely and completely (using data sanitisation standards outlined in 'DoD 5220.22-M' - this is a software-based data sanitisation method used in various file shredder and data destruction programs to overwrite existing information on a hard drive or other storage device. The Data Asset Register will be updated to confirm destruction of the data.

At ICF, on completion of an assignment, all sensitive data held in electronic format will be destroyed, using the 'secure deletion' feature which is part of PGP Netshare.

RECORD RETENTION AND ARCHIVING

Quantitative and qualitative evaluation

Any paper records will be kept in a locked cabinet throughout the course of the study. All data collected and stored electronically will be held on secure servers on the premises of the CI and co-investigators.

At the end of the evaluation, these records will be archived to a secure unit and retained for 7 years.

STATEMENT OF CONFIDENTIALITY

Quantitative and qualitative evaluation

Individual participant information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to data in the computer files.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the funder, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Quantitative and qualitative evaluation

Three reports will be produced for this evaluation:

- An interim report, in draft in January 2019, for finalisation in March 2019.
- The main report, in draft in October 2019, for finalisation in December 2019.
- Final synthesis report in April 2020, for finalisation in June 2020.

Interim report

The interim process evaluation report will provide the findings from the Time 1 qualitative fieldwork. It will make initial recommendations to inform the roll out of EA in IAPT in Wave 2 areas.

Main report

The main report will build upon the interim, and draw together findings from the Time 1 and 2 qualitative fieldwork, and the findings from the client Wave 1 quantitative survey. It will provide evidence based conclusions and recommendations regarding: implementation (as intended, working well/less well, impact of the 1: 8 ratio); the range of support provided, with staff and client experiences of delivery; and impacts and influences for both clients (outcomes) and staff (time released, new partnerships formed).

Synthesis report

This report will present findings from the Time 2 surveys and the results of the analysis identifying the net impact of additional Employment Advisers in IAPT on clients' health and work outcomes.

Participants will not be identified in any publications.

The synthesis report will be published on the GOV.UK website.

STUDY FINANCES

The funding source is the Work and Health Unit, a joint unit between the Department for Work and Pensions and Department of Health and Social Care.

Participant stipends and payments

Quantitative evaluation

There are no incentives provided for the quantitative evaluation

Qualitative evaluation

Clients taking part in qualitative interviews will receive a £15 high street voucher as a thank you for their time.

SIGNATURES

Signatories to Protocol:

Chief Investigator: (name)_____

Signature:_____

Date: _____

Funder: (name)_____

Signature:_____

Date: _____

Bibliography

[i] Royal College of Psychiatrists (2013) *Mental Health and Work*

[ii] ONS, NHS England (2014) Adult Psychiatric Morbidity Study. Common mental disorders are characterised by a variety of symptoms such as fatigue and sleep problems, forgetfulness and concentration difficulties, irritability, worry, panic, hopelessness, and obsessions and compulsions, which present to such a degree that they cause problems with daily activities and distress

[iii] DWP (2016) *Work, Health and Disability Green Paper - Data Pack*

[iv] Nomis data for ESA claimants August 2016. Note this benefit is being replaced by Universal Credit.

[v] DWP Work and Pensions Longitudinal Study, DWP Tabulation Tool February 2016

[vi] DWP, https://www.gov.uk/government/collections/disability-confident-campaign, November 2016

[vii] Royal College of Psychiatrists (2013) *Ibid.*

[viii] Work and Pensions Select Committee (2017) *Report: Disability employment gap*

[ix] Coleman N, Sykes W, Groom C. (2013) *What works for whom in helping disabled people into work?* DWP Working paper 120

[x] DWP/DoH Command Paper (2017) I

[xi] NHS England (2016) *The Five Year Forward View For Mental Health*

[xii] Waddell, G. & Burton, A.K. (2006) Is work good for your health and wellbeing? Norwich: The Stationary Office.

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