Trust Board Meeting	July 2020
Title	Research and Development Annual Report 2019/20
Purpose	This report presents a summary of research and related activity for the year 2019/20
Business Area	Corporate (Medical Directorate)
Author	Katie Warner, Head of Research and Development
Relevant Strategic Objectives	True North goals of Harm free care, Supporting our staff, Good patient Experience and Money Matters
CQC Registration/Patient Care Impacts	Clinical research provides patients with access to the latest care, treatments, medication and therapies. It also provides patients, carers and staff members with opportunities to contribute to the generation of evidence to improve current best practice and identify new and improved treatment options offering better outcomes. The CQC have now included key research questions with the 'well-led' domain of their inspection framework.
Resource Impacts	The Research and Development department are predominantly funded by the National Institute for Healthcare Research (NIHR). The majority of this is Activity Based Funding (ABF) and is received via the Local Clinical Research Network (CRN) Thames Valley and South Midlands. This is then supplemented by NIHR Research Capability Funding (RCF), a small commercial income and some trust finance. Funding is allocated annually and a number of team members hold short term contracts as funding is based on previous years' research activity.
Legal Implications	Operating according to the UK Policy Framework for Health and Social Care Research. This includes maintaining compliance with relevant UK legislation when conducting research and ensuring all Trust Research Governance processes are aligned to Health Research Authority (HRA) Approval processes.
Equality & Diversity Implications	Berkshire Healthcare is committed to delivering the objectives of the National Institute for Health Research (NIHR) to continue to increase patient equality in terms of access to clinical trials. The Research and Development (R&D) department's long-term vision is to offer research participant opportunities to all Trust patients.
SUMMARY	This report details BHFT research activity for the current financial year in comparison with the past four years. Impacts, benefits, communications and participant experience are noted. Details of finance, structure, operations and performance are also provided.
Action required	The Board is asked to note the contents of the report, progress made during the year and future direction for the coming year.

Research and Development Annual Report Template

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1. Executive Summary

Berkshire Healthcare NHS Foundation Trust (BHFT) is a research active organisation. Our aim is for all patients to have access to research opportunities which are relevant to them. In 2019/20 we ranked 7th out of the 49 benchmarked mental health and community trusts for the volume of research activity that we provide.

In the last four years we have delivered 174 research projects, including 79 in 2019/20. This includes a range of research from smaller scale student projects involving a subsection of our patients to national multi-centre clinical trials involving numerous NHS sites. Much of our research is observational, led by another non-commercial entity such as an NHS Trust or University and involves adult mental health services. Nursing and medical staff provide leadership in roughly equal measure to the research projects which take place with either BHFT patient, staff, carers or data. They are closely followed by Psychological Therapists. Local smaller scale research projects tend to be driven by PhD students and Clinical Psychology Doctoral trainees placed at local/regional universities.

By BHFT participating in research our patients are provided with access to assessments, treatments and interventions which they would not otherwise receive as part of routine care. Staff, patient and carers are also able to contribute to the evidence base for conditions which are most of interest to them. 96% of our research participants in 2019/20 strongly agreed or agreed that they had had a good experience of taking part in the research study.

The Research and Development (R&D) department is working hard to address all elements of equity of access including ensuring research opportunities are accessible in all clinical areas, to all patients, carers and staff as far as study eligibility criteria and sample sizes allow us to. We are also working to better understand what research opportunities patients in neighbouring organisations have access to and are mirroring these where possible.

Research opportunities relating to current open studies and available support for staff members undertaking their own projects are communicated and promoted through induction, social media, our webpages, intranet, posters in waiting rooms, team meetings and attendance at key events.

During 2019/20 we had 30 full or part time permanent or fixed term research nurses/AHP's, clinical research practitioners and assistants who were either based in clinical services or with the R&D department core team. The vast majority of our funding is provided by the NIHR Local Clinical Research Network (LCRN): Thames Valley and South Midlands.

We have continued to review our governance arrangements including research activity oversight, standard operating procedures, policies, monitoring and data management. This has resulted in the development of a new process for Trust sponsored research studies and a comprehensive audit plan.

Externally specified performance objectives were achieved, however we had difficulty attracting and recruiting patients and carers to Dementia and Neurodegeneration studies. This reflects the national picture. We continue to work with services to support the CQC clinical research requirements which feature in the well-led framework focussing on equity, facilitation and awareness.

The BHFT R&D department are proud to be involved in numerous partnerships and collaborations and look forward to further aligning with BHFT core priorities in 2020/21 via our plan on a page. In particular offering research opportunities in the areas of self-harm, suicidality, pressure ulcers, falls and COVID-19 and embedding new remote working practices in addition to developing our strategy.

2. Introduction

Clinical research involves gathering information from patients and healthy volunteers to improve the medications, therapies and services that we offer to patients. By participating in clinical research, patients may be able to access assessments and treatments that are not available as part of routine NHS care.

Research is an integral component in the delivery of Trust priorities. Specifically, involvement in clinical research is one way that we demonstrate our commitment to actively improving the clinical treatments, care and outcomes for our patients and providing safer services. Research into new ways of working and technologies can assist us in delivering more efficient and financially sustainable services. Supporting our staff in the delivery of research has the potential to strengthen skills and increase engagement.

Berkshire Healthcare has a well-established portfolio of research which is updated regularly as new research projects open and close. Research projects at Berkshire Healthcare last from several months to several years depending on the nature of the study. Projects involve patients, staff, carers and members of the public.

Our aim is for all patients to have access to research opportunities which are relevant to them. During the course of 2019/20 our patients were able to access research relating to bipolar disorder, dementia, eating disorders, autism, diabetes, schizophrenia, Chronic Obstructive Pulmonary Disease, Post Traumatic Stress Disorder, Attention Deficit Hyperactivity Disorder, anxiety and depression.

We have implemented a robust research governance system to ensure research is designed, conducted and delivered to the highest standards. We continually improve and monitor this system to ensure it is fit for purpose.

3. Research and Development at BHFT - the last 4 years

3.1 Number of Research Projects

In the last four financial years 1st April 2016 - 31st March 2020 Berkshire Healthcare conducted 174 research projects. Some of these projects overlapped financial years but have only been counted once. A period of four financial years has been chosen as we feel confident in the accuracy of the data captured in relation to the research projects for this period. In the last financial year 1st April 2019 - 31st March 2020 Berkshire Healthcare conducted 79 research projects. 42 research projects were set up in 2019/20 (26 NIHR portfolio and 16 non-NIHR portfolio, see below for distinction). A list of 2019/20 research projects and summaries can be found in Appendix 1.

3.2 NIHR portfolio v non-portfolio

Most of the research studies that we invite our patients to participate in are National Institute of Health Research (NIHR) portfolio studies. The NIHR portfolio is a national list of high-quality studies which have received particular sources of funding. We receive external funding to deliver NIHR portfolio projects. Our other high-quality research studies (non-portfolio projects) are conducted in part fulfilment of qualifications e.g. MSc or by a member of staff but will not have received funding from a relevant funding source. We receive internal Trust funding for part of the salaries of our Research Governance Facilitator and R&D Manager to enable us to support the set up and governance of these projects which have not been adopted onto the NIHR portfolio.

All research has a sponsoring organisation. By sponsoring the research the organisation is accepting overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. Historically BHFT have not acted in the role of sponsor very frequently. There have only been six occasions in the last four years where BHFT have acted in the role of sponsor. Three of these projects were open in the last financial year.

In the last four years BHFT have worked on 112 portfolio and 43 non-portfolio research projects. There are an additional 19 projects where project type will need to be confirmed. In 19/20 we worked on 57 portfolio and 22 non-portfolio projects. Some of these were in active recruitment phase whilst others were in follow up phase.

3.3 Professional Group of the Principal Investigator

All research projects should have a Chief Investigator and if operating at multiple sites (e.g. different NHS Trusts), a Principal Investigator (PI) should be in place at each research site. On analysing the professional backgrounds of Principal Investigators over the last four years we found that 38 were nurses, 32 were medics, 30 were Psychological Therapists (including Psychologists and Psychotherapists), 17 were R&D staff members from unqualified clinical backgrounds (low risk, low complexity studies and usually termed Local Collaborator rather than PI) and 6 were Allied Health Professionals. A further 2 were other professionals and in the case of 49 research projects the professional group which the Principal Investigator belonged to was not recorded. It should be noted that work is ongoing to ascertain the professional groups of these individuals to further enrich future analysis.

The proportions of each professional group acting as Principal Investigator are reflective of the latest financial year 19/20. 18 Principal Investigators were medics, 19 were nurses, 13 were Psychological Therapists and 8 were R&D staff from unqualified clinical backgrounds. 2 were Allied Health Professionals and in 19 cases the professional group was not recorded.
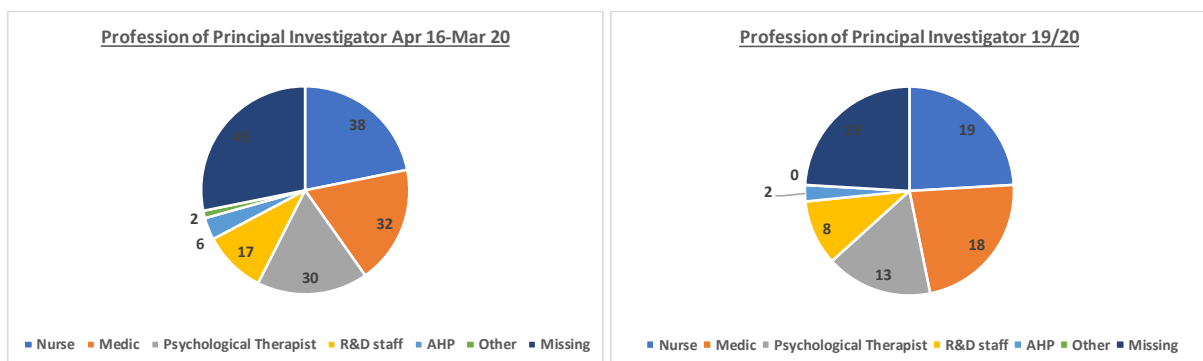
3.4 Interventional v Observational research

The majority of BHFT research is observational. Research projects termed as interventional studies are those in which patients receive specific interventions in line with the research protocol. Observational studies are those in which the investigators do not seek to intervene, but simply observe the course of events.

In the last four years BHFT have conducted 122 observational studies, 51 interventional studies and one study did not have the research type recorded. This compares to 19/20 when 11 interventional and 68 observational studies were undertaken.

3.5 Commercial v Non-Commercial

The majority of the research that BHFT undertakes is non-commercial Research. This is for a number of reasons in particular neighbouring Trusts being better established, with enhanced facilities and more expertise and experience in commercial trials e.g. London and Oxford Mental Health and Community Trusts. This makes it difficult to compete when submitting expressions of interest. In the last four years BHFT undertook 10 commercial and 159 non-commercial research projects. Data was missing for 5 research projects. Of the 10 commercial research projects, BHFT were a Patient Identification Centre (PIC) rather than a full site in three cases. This means we explain the study to potential participants and with their permission forward their contact details to the study team to undertake the detailed consent procedure and deliver the research project. We would act as a PIC site where we have the patient population but not necessarily the expertise, experience and/or facilities to deliver the research ourselves.

In 2019/20 we undertook 5 commercial and 74 non-commercial research projects. In three cases we acted as Patient Identification Centres for studies on the NIHR portfolio and in the remaining two cases we acted as a site for non-portfolio commercial studies.

The department expressed an interest in nine Commercial NIHR Portfolio and Non-Portfolio Trials in 2019/20 (see table below). We hosted two non-portfolio commercial trials (sponsored by Silvercloud Health) and supported three studies as a Participant Identification centre (PIC).
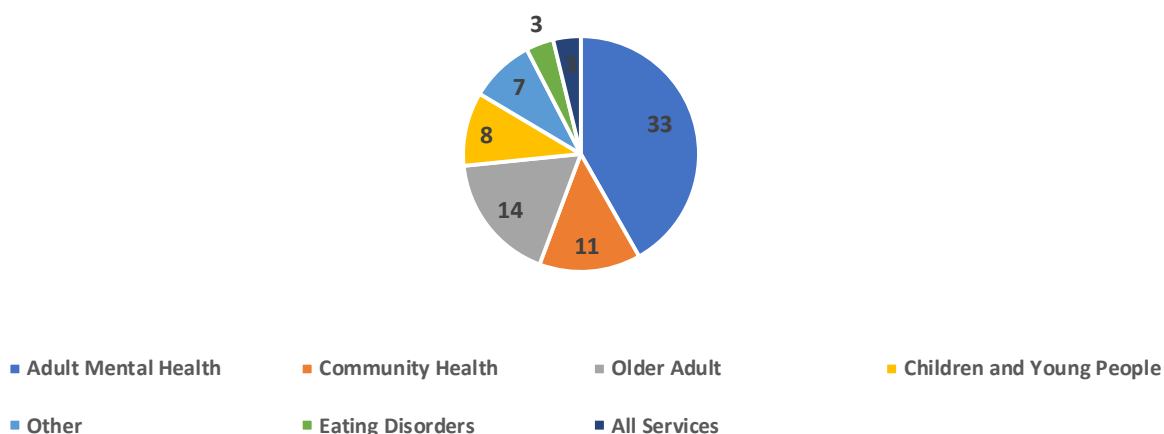
Studies the department expressed an interest in 2019/20

ID Number	Study Summary	Type of expression of interest submitted	Success
MENT 37773	Improving Access to Psychological Therapy: An examination of outcomes across three step 2 low intensity psychological treatment intervention	Site Intelligence	Successful
MENT 41399	Internet-delivered CBT intervention for perinatal depression and anxiety: a pilot trial	Site Intelligence	Successful
MENT 43228	A phase II randomized, double-blinded, placebo controlled parallel group trial to examine the efficacy and safety of 4 oral doses of BI 1358894 once daily over 12 week treatment period in patients with Borderline Personality Disorder	Site identification	Unsuccessful
MENT 40219	A Phase 2, Randomized, Double-Blind, Multiple-Dose, Placebo-Controlled Study to Evaluate the Safety and Efficacy of BIIB104 in Subjects With Cognitive Impairment Associated With Schizophrenia (CIAS)	Site identification	Unsuccessful
MENT 43198	An Observational, Prospective UK Study Examining Clinical Outcomes of patients, Carer Burden and Direct Health Care Costs for Patients with Symptoms of Moderate to Severe Major Depressive Disorder (MDD) that have Active Suicidal Ideation with Intent	Site identification	Successful
DEME 43189	Surrogate biomarkers from speech and language for successful clinical trials in presymptomatic and preclinical Alzheimer's (ADVOX 1)	Site identification	Unsuccessful
CHIL 35805	Bumetanide in Children with Autism Spectrum Disorder	Site identification	Successful
MENT	Understanding the information practices and data needs	Site identification	Successful
MENT	Precision in Psychiatry Study (PIPS)	Site Identification	Successful

3.6 Studies broken down by recruiting service area

A large proportion of the active research projects recruit from Adult Mental Health Services, followed by Older Adult, Community Health and Children and Young People. This is true for the last four years as well as the most recent financial year 2019/20.

Service Area Where Research Project Recruited Participants From Apr 16-Mar 20

Service Area Where Research Project Recruited Participants From 19/20

Legend:
- Adult Mental Health
- Community Health
- Older Adult
- Children and Young People
- Other
- Eating Disorders
- All Services
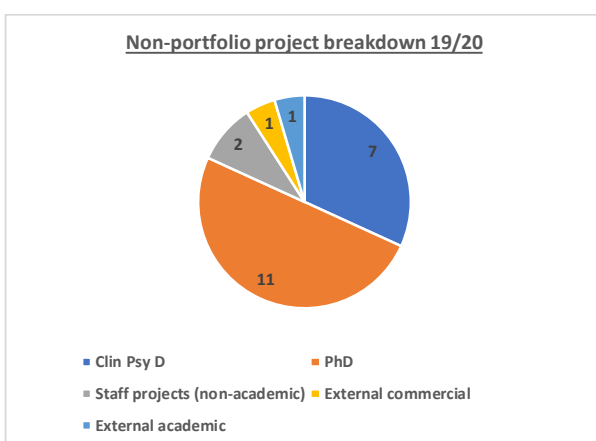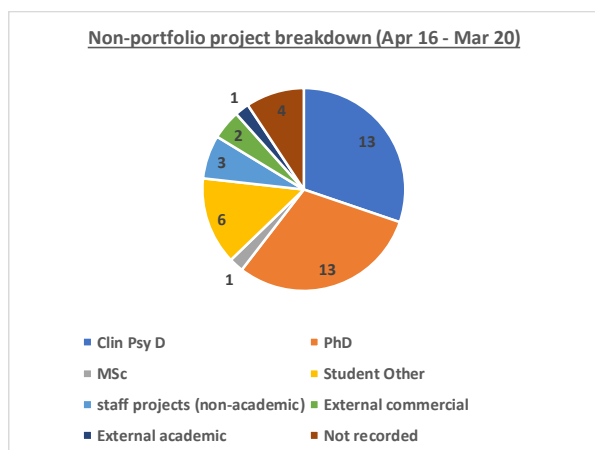
Values shown: 33, 11, 14, 8, 7, 3

In 2019/20 'other' includes research projects which recruited from Learning Disabilities, Corporate and joint Adult and Older Adult mental health services project.

3.7 Non-portfolio project breakdown

The 43 non-portfolio projects which took place in the last four years were conducted as part of a Clinical Psychology Doctorate (13), MSc (1), PhD (13) and other academic courses (6). In addition three projects were undertaken by staff not linked to academic courses, two were undertaken by an external commercial company/BHFT service and another by an external academic. In four cases this information is not recorded.

In 19/20 11 of the 22 active non-portfolio research projects were conducted as part of PhD and seven were conducted as part of Clinical Psychology Doctorate courses. The remaining projects were staff projects not linked to an academic course (2), external academic (1) or external commercial (1).

Non-portfolio project breakdown (Apr 16 - Mar 20)

Values shown: 13, 13, 1, 6, 3, 2, 1, 4

Legend:
- Clin Psy D
- PhD
- MSc
- Student Other
- staff projects (non-academic)
- External commercial
- External academic
- Not recorded

Non-portfolio project breakdown 19/20

Values shown: 7, 11, 2, 1, 1

Legend:
- Clin Psy D
- PhD
- Staff projects (non-academic)
- External commercial
- External academic

3.8 Portfolio project breakdown (graphs provided by Local Clinical Research Network (LCRN): Thames Valley & South Midlands)

When we look specifically at the NIHR portfolio projects which we have recruited to in recent years the term large scale is also noted as a project category by the CRN which refers to large scale surveys. Within our data sets we have termed these observational although recording will be brought into line with NIHR LCRN practices in future reports. Please note the number of portfolio projects captured by the LCRN is lower than that recorded as part of our own systems above. This is

because LCRN figures relate to those studies which were recruiting only, by contrast, we have noted all NIHR portfolio projects which were open to ensure the total volume of research activity is understood within BHFT. This would include projects in recruitment, in follow up and where we acted as Patient Identification Centres only.

Participant Recruitment to NIHR Portfolio Studies at BHFT (excluding commercial)

Number of Recruiting NIHR Portfolio Studies at BHFT (excluding commercial)
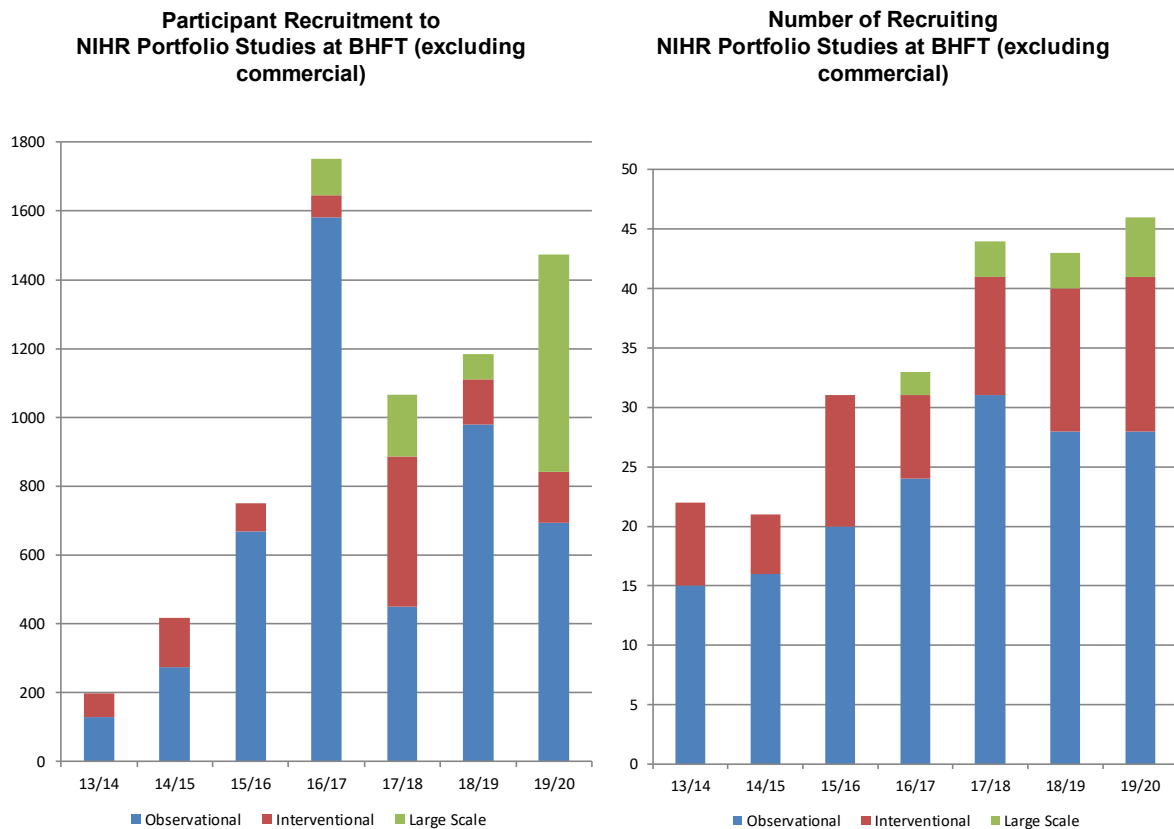
3.9 Further Analysis

Future reports will feature analysis by 1) specialty area and/or condition e.g. bipolar disorder or diabetes services 2) further service area breakdown 3) participant breakdown e.g. patient, staff, carer 4) recruitment numbers where possible.

3.10 Partnership Working- the last four years

Partnership working is of paramount importance to the research we deliver in Berkshire Healthcare. We have worked with 41 universities and 20 NHS organisations over the past four years to bring research opportunities to patients, staff and carers of Berkshire Healthcare (see appendix 2 for details). The relationship with these institutions was in their role as sponsor, employer of the Chief Investigator or base for the study team. Further information on partnership working and collaboration can also be found in section 12 of this report.

Berkshire Healthcare are also members of the UK Research and Development (UKRD) which is a community of R&D Leaders, colleagues with responsibilities to Board for the R&D function in their organisation. Currently the group is feeding their expertise into key government departments to inform ministerial discussions. Our involvement in this group is via the Head of R&D. In addition, a number of staff members in the R&D department link into the NHS R&D Forum (RDF) which is a UK–wide community of practice and professional network for the health and care research management, support and leadership workforce.

4. Impacts and Benefits- What difference did it really make

The current report and previous annual reports have evidenced the high level of research activity which takes place at Berkshire Healthcare NHS Foundation Trust with staff, patients, carers and the public acting as research participants.

Evidence show clinically research active hospitals have better patient care outcomes (Boaz et al, 2015; Jonker & Fisher, 2018; Jonker et al, 2019. However, it is important to ensure that we are clear on the outputs and outcomes of the research that BHFT have been involved in. This will ensure our efforts and resource amount to time and money which is well invested for the benefit of those we serve and who work within our organisation.

To this end, this year we have provided further analysis to help us to better understand the benefits and impacts of the research that BHFT patients, carers and staff have participated in and supported in recent years. A summary can be found below and further details and links to findings from studies that we have participated in will be available on our website shortly.

Our analysis comprised a review of documents which have been published by members of the study teams for closed or long-term open NIHR portfolio projects that we have participated in. These include NIHR reports, peer-reviewed journal articles, guidance documents and other reports.

In summary we can say that the research that we have been involved in previously has resulted in:

- Developing and assessing a tool to understand emotional well-being and need for support for carers of people with dementia.
- Further understanding of the effectiveness of medication in the treatment of Alzheimer's.
- Identifying a valid and reliable new quality of life questionnaire which more adequately considered the impact of long-term health conditions.
- Better understanding stigma and equality for those living HIV/Aids. This information has been used to inform government reports.
- Improving the understanding regarding the neuroscience of Alzheimer's Disease with a view to reviewing current treatments, developing new treatments and a greater understanding of potential treatments.
- Building a repository of information including socio-economic, environmental impact and social support on cognitive decline in dementia.
- Better understanding the delays that can be experienced in providing support and moving forward to improve the experience and quality of life for individuals with young onset dementia. This has resulted in the production of guidance on good practice.
- Individuals with dementia co-producing research regarding medications management. The Alzheimer's Society use this as an example to recommend getting involved in research.
- Identifying clinician related barriers to supporting children with PTSD.
- Better understanding the psychological treatment of panic disorder in adolescence.
- Providing a bespoke smoking cessation intervention for people with severe mental illness.
- Better understanding the complexities of the presentation of patients with psychosis.
- Validation of measures to assess suitability for psychological therapies for distressing voices.
- Developing an online self-help toolkit for friends and relatives of people with mental health problems associated with Psychosis or bipolar disorder.
- Understanding more about contingency management as an intervention for reducing time to acute psychiatric admission or reducing cannabis use in psychosis.

Please note that it has not been possible to obtain outputs and outcomes for all previous research projects that we have participated in due to some projects not having yet published their findings. We will continue to build our repository of outcomes and impacts and share these routinely with BHFT patients, carers and staff. Example service reports which we plan to use to keep staff members up-to-date on research in their areas can be found in appendix 4. We will be trialling these 20/21.

Research that we are currently involved in aims to:

- Explore the psychological impact of COVID-19 outbreak and the resultant restrictions in terms of behavioural, emotional and social factors.
- Better understand current attitudes, practices, training needs, and perceived barriers and facilitators to address and implement smoking cessation treatments.
- Understand the cause and prevalence of memory problems in people with mental health, neurodevelopmental and neurodegenerative disorders.
- Explore and identify themes around how females with both Autistic Spectrum Disorder (ASD) and Bipolar Disorder (BPD) perceive self-harm, abandonment and their diagnosis, in order to learn more about the overlapping features of ASD and BPD.
- Explore clinical efficacy and dose response of a medication for use in Alzheimer's Disease.
- Explore patient preferences for psychological therapies for hearing distressing voices.
- Test automated virtual reality cognitive therapy for patients with fears in social situations.
- Establish the prevalence of pathogenic antibodies in patients with first episode psychosis.
- Understand the views and preferences of staff working in the CRHTT regarding the use of Brief Suicide-specific Psychological Interventions (BSPI) within a Crisis Resolution and Home Treatment Team (CRHTT) service.
- Evaluate whether training in brief suicide-specific psychological interventions (BSPI) with Mental Health Practitioners within a Crisis Resolution and Home Treatment Team (CRHTT) service to support suicidal patients produces measurable changes in nursing practice and patient care.
- Establish patient and public views on the sharing of identified NHS/HSC health data (for clinical purposes) and de-identified health data (for research) within the UK.
- Evaluate the clinical and cost effectiveness of a standardised diagnostic assessment (SDA) tool as an adjunct to usual clinical care in children and adolescents presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS).

Please note: only a selection of current research project aims are included above.

We can conclude that as a research active Trust BHFT are providing:
- **Patients** with the opportunity to receive assessments, treatments, therapies and interventions that they would not otherwise have received as part of standard care.
- **Carers** with the opportunity to share their experiences and support their loved ones to participate in research.
- **Staff** with the opportunity to share their experiences, preferences, training needs and barriers re: the delivery of current services and interventions as research participants.
- **Staff** with the opportunity to drill down thoroughly into an area of concern where Quality Improvement, Audit or Service Evaluation methodologies are not sufficient.
- **All research participants** (including the general public for some studies) the chance to contribute to the evidence base on topics that are important to them.
- **Our organisation** with the opportunity to receive funding to provide all of the above opportunities and to support staff interested in research to lead or participate where relevant.

65 publications, which include BHFT staff members as authors, were identified in 2019/20 by the BHFT Library Service. Please see Appendix 3 for list of 2019/20 publications.

5. Experience of Research Participants - What do research participants tell us?

All NHS Research Departments are required to take part in the national Participant Research Experience Survey. This is developed and led by the National Institute for Healthcare Research (NIHR) and supported locally by the NIHR Local Clinical Research Networks.

BHFT are set a target for the number of survey responses that we need to collect and each year the Research and Development staff members work to promote the survey amongst the research participants that we engage with. It should be noted that where studies are accessed online or anonymously it is more difficult to contact the research participants to promote the survey.

This year our target was 30 survey response, but we collected 106 responses in total. This is 7% of the total number of research participants who accessed a research opportunity with BHFT.

The key findings for BHFT as compared to the wider Thames Valley and South Midland region are as follows:
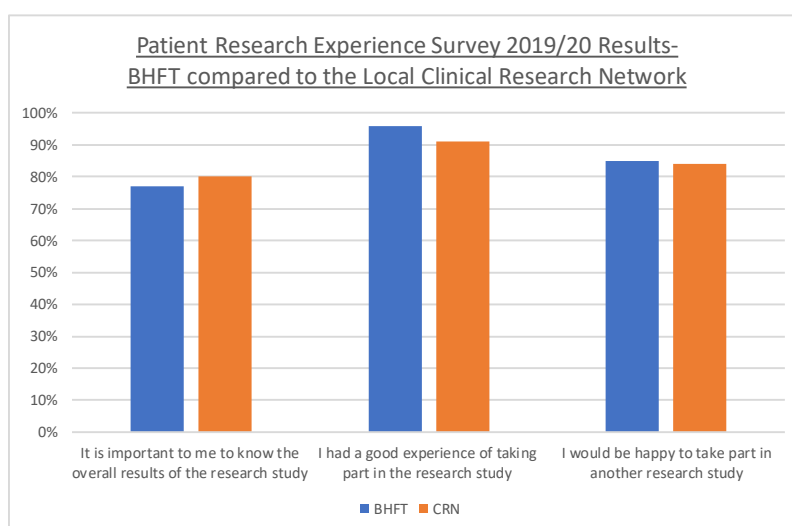
- The most popular reason for why participants took part in research was to help others (44% BHFT; 39.5% LCRN).
- Most respondents (77% BHFT, 80.1% LCRN) agreed or strongly agreed that it was important to them to know the overall results of the research study.
- Most (96% BHFT, 91.1% LCRN) strongly agreed or agreed that they had had a good experience of taking part in the research study.
- Most respondents (85% BHFT, 84.3% LCRN) agreed or strongly agreed that they would be happy to take part in another research study.

We have also received feedback from our research participants which have been captured in case studies by the communications team at the LCRN. Links to the full publicly available case studies are provided at the bottom of the page.

Research Participant Feedback

"There's so many people with dementia who feel like me and I want to do what I can to help them."

"We wanted to take part in research so there's more insight into the illness and if other people can benefit from it, that's brilliant.

""I realise you can't change this condition, but you can let people know what it does to you. Research is the only way we're going to make any sort of progress."

"That study opened up lots of ideas of things we can do together and enjoy. By taking part in research, not only are you helping others, but you can find information that might help you. I wouldn't have thought to do that, but his memory was a lot better afterwards."

"I've been through many years of misdiagnosis and I think it's quite good to be involved in research for that reason. There wasn't the same understanding of mental health at the time."

To read real-life stories in full from those participating in research from Berkshire Healthcare and the wider Thames Valley and South Midlands region please use the following link: https://local.nihr.ac.uk/lcrn/patient-stories/?custom_in_LCRN=22640

What will we do with our research participant experience information?

The feedback from the research participants who took part in the national survey was overwhelmingly and comparatively positive. Potential improvements to our service to further improve participant experience have been suggested by the R&D team. These include:

- Providing feedback about the results of the research projects that people have participated in routinely in a more structured and accessible way.
- Reviewing the procedures that we have in place to ensure that participants do not become 'research tired'. This should include adequate monitoring of participants who are approached for multiple research projects, ensuring participants would like to remain registered on our research interest list and ensuring continuity of researcher where possible.
- Develop our offering to ensure that patients and the public can be involved in all stages of the research process at BHFT.

6. Equity of Access- What we know about equity of access to research opportunities at BHFT

Equity of access is of key importance to BHFT. One of the strategic objectives in the BHFT Equality and Diversity strategy (2016-20) states: "We want to engage with diverse groups in particular BME, LGBT and disabled people to inform our understanding of their needs, ensuring a good patient experience and equity of access in both mental and community health".

Equity of access is one of the principles by which the work of the NIHR Coordinating Centre and Local Clinical Research Networks are guided: "We work to ensure patients, carers, the public, and healthcare professionals....have opportunities to participate in and benefit from the widest range of high-quality health and social care research studies.....people should have the opportunity to participate in studies relevant to their health condition, conducted in accessible locations".

The BHFT R&D department aims to provide as many people as possible with research opportunities i.e. access to the latest treatments, interventions and assessments which would not otherwise be available as part of standard care. In 2019/20 we ranked 7th out of 49 Trusts for the volume of high-quality research projects that we recruited participants into. We offer more opportunities for research participants to participate in observational and non-commercial studies compared to interventional and commercial studies but are working to provide greater access to interventional and commercial studies. This will be balanced with needs and priorities of our patients and carers.

Wherever possible we invest in a range of clinicians who are embedded within clinical services to support the development and delivery of research rather than within a central R&D department. This helps to provide local access to opportunities which are relevant to local populations. In 19/20 clinicians were funded to undertake research in Older Adults, CAMHS, Talking Therapies, Sexual Health, Learning Disabilities, Perinatal, Cardiac and Respiratory and Diabetes Services. These clinicians are located across the county of Berkshire from Thatcham in the West to Slough in the East, work in many settings- hospitals, clinics, community bases, universities and people's homes.

Whilst aiming to provide research opportunities to all as part of routine care we also maintain a Research Interest List (RIL) which clinicians can refer to/patients and carers can sign up to in order to receive information about relevant research projects. The national 'Join Dementia Research (JDR)' database is also accessed in order to identify local research interested individuals.

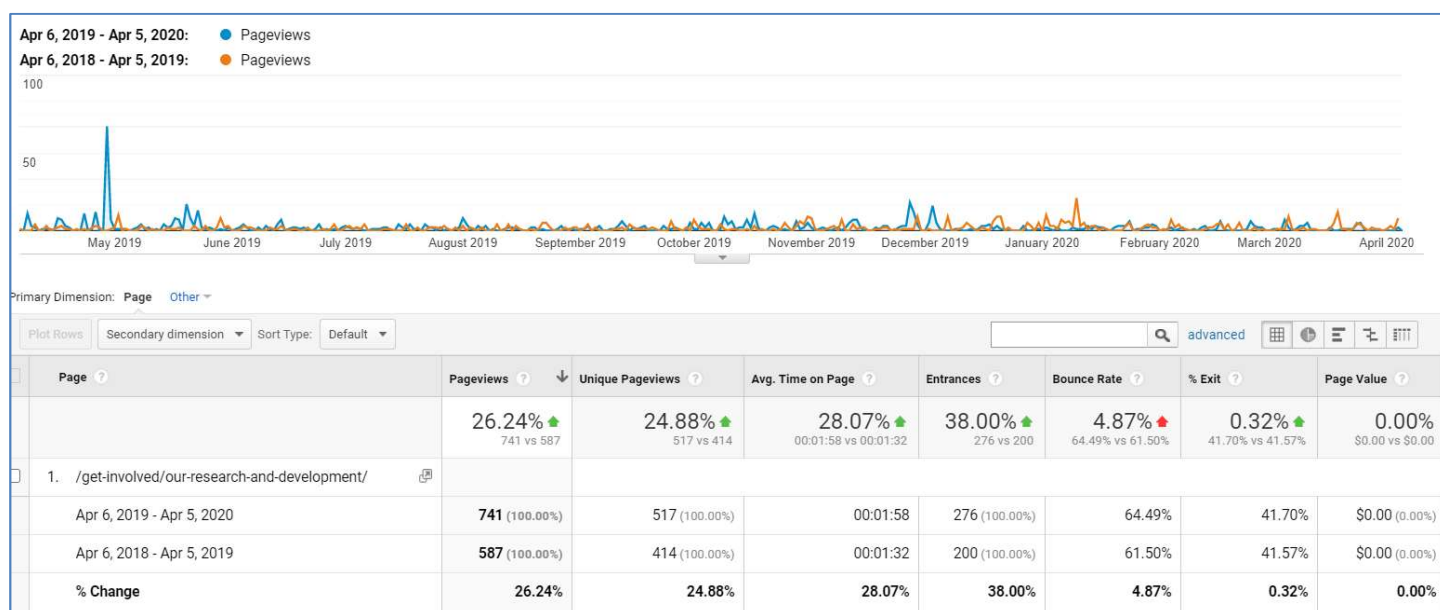The following areas are being explored to better understand equity of access in R&D:

Question	Current knowledge	Next steps
To what extent are research opportunities available across BHFT?	Lead Research Nurse or Clinical Research Practitioner providing oversight Trustwide. Research staff employed in some Trust services.	Consider feasibility of having dedicated research active individuals in each service area.
To what extent is our Research Interest List representative of the communities we serve?	80% of our RIL is comprised people age 65+ due to the list originating in older adult services. There is a fairly even split between genders. 75% are British and whilst the majority of localities in Berkshire have 13-16%, Wokingham residents account for (23%) of interested individuals.	Research interest question is being incorporated into forms on RiO. This should increase the number of people who are able to be contacted about research opportunities significantly.
How representative are our research participants of the communities we serve?	This is difficult to analyse as many research participants sign up online or data goes directly to the study team in line with the consent process. Study eligibility criteria is key to identifying and providing access to participants.	Ensure that our RIL is representative and that individuals are told about research projects as part of routine care. Challenge study teams where groups are excluded.
To what extent are Berkshire residents able to access the same opportunities as those in neighbouring counties?	Each Trust provides slightly different research opportunities. This is based on local needs, expertise, funding, required samples and networks but equity of access can be improved.	Review neighbouring Trust research portfolios to identify inequity. Work together to provide greater equity where possible.

7. Communication and Promotion- How do we promote and communicate research at BHFT?

The Research and Development team continually promote research and related opportunities.

Website – a list of open research studies has been added to our webpages and some content updated. We are currently reviewing our webpage which will be updated further in 20/21. Our web metrics report is presented below. Spikes in figures are often due to social media posts, news items, or the team attending an event. External variables such as time of the year and news reports (e.g. BBC report on a new vaccine) can also lead to people Googling our services. Highlights include:

- Increase in unique pageviews (24%)
- Users spending longer on the page (~26 seconds more on average)
- Significant spike noticed in May, potentially due to #IAmResearch campaign
- In 19/20, more users went on to the 'take part' page (119) compared to 18/19 (58)

Page	Pageviews	Unique Pageviews	Avg. Time on Page	Entrances	Bounce Rate	% Exit	Page Value
	26.24% ▲ 741 vs 587	24.88% ▲ 517 vs 414	28.07% ▲ 00:01:58 vs 00:01:32	38.00% ▲ 276 vs 200	4.87% ▲ 64.49% vs 61.50%	0.32% ▲ 41.70% vs 41.57%	0.00% $0.00 vs $0.00
1. /get-involved/our-research-and-development/							
Apr 6, 2019 - Apr 5, 2020	741 (100.00%)	517 (100.00%)	00:01:58	276 (100.00%)	64.49%	41.70%	$0.00 (0.00%)
Apr 6, 2018 - Apr 5, 2019	587 (100.00%)	414 (100.00%)	00:01:32	200 (100.00%)	61.50%	41.57%	$0.00 (0.00%)
% Change	26.24%	24.88%	28.07%	38.00%	4.87%	0.32%	0.00%

Social media: We are increasingly using social media platforms to promote research and specific research participation opportunities. Specifically, Twitter, Facebook and LinkedIn.

Post
International Clinical Trials day – our team visiting hospitals across the region
International Clinical Trials day – find out more about our research
International Clinical Trials day – research helps us develop new treatments – find out more
Our R&D team share what research means to them
Our R&D team were at Broad Street Mall
Promoting a study to people who provide caring support for a loved one with psychosis
Social media posts to inform participants of a potential Bipolar Disorder study

Promotional events and initiatives attended by the R&D department – 19/20
- 5th Annual Primary Care Research Symposium, Green Park Conference centre.
- Raising awareness at Oracle shopping centre on February 2020.
- Work to improve the information provided to services regarding relevant open research studies. Beginning in memory clinics, this included posters in waiting areas and Psychology Assistant support for clinicians to help identify patients who may be eligible for specific studies.
- Monthly Trust induction and Junior Doctors Induction
- Psychological Therapies Research Showcase event at UoR for BHFT Psychological Therapies staff. The purpose of the event was to share and thank staff members for their research contributions.

8.   People and Finances- Who delivers research at BHFT and how is it funded?

8.1 R&D department structure and staffing

The core BHFT R&D team are based at the University of Reading in the School of Psychology and Clinical Language Sciences.

Our core team comprises:

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                    ┌─────────────────────────────────────┐
                    │     Executive Medical Director       │
                    └──────────────────┬──────────────────┘
                    ┌──────────────────┴──────────────────┐
                    │ Head of Research & Development (0.6wte)│
                    └──────────────────┬──────────────────┘
                    ┌──────────────────┴──────────────────┐
                    │ Research and Development Manager (1wte)│
                    └──────────────────┬──────────────────┘
```

| Lead Clinical Research Practitioner (1wte)	Lead Research Nurse (0.8wte)	Research Governance Facilitator (1wte)
Adult Mental Health, CAMHS, Talking Therapies and Learning Disabilities	Older Adult and Community Health Services	Governance, data, reporting, administration
Clinical Research Practitioners, Research Fellow, Research Assistant and Clinical Studies Officer	Clinical Research Practitioners, Research Nurses, Research Physio, Student Nurse and Research Assistants	

The Head of Research and Development joined the department in May 2019. During the course of 2019/20 we have had 30 full or part time permanent and fixed term research nurses/AHP's, clinical research practitioners and assistants who are either based in clinical services or with the R&D department core team. Posts vary each year depending on turnover, research funding and requirement. The majority of staff funding comes from the NIHR LCRN (19 posts; 12.1wte in 18/19 and 23 posts; 11.5wte in 19/20). Additional funding is provided by individual project income (see below) and BHFT contribution (£33k).
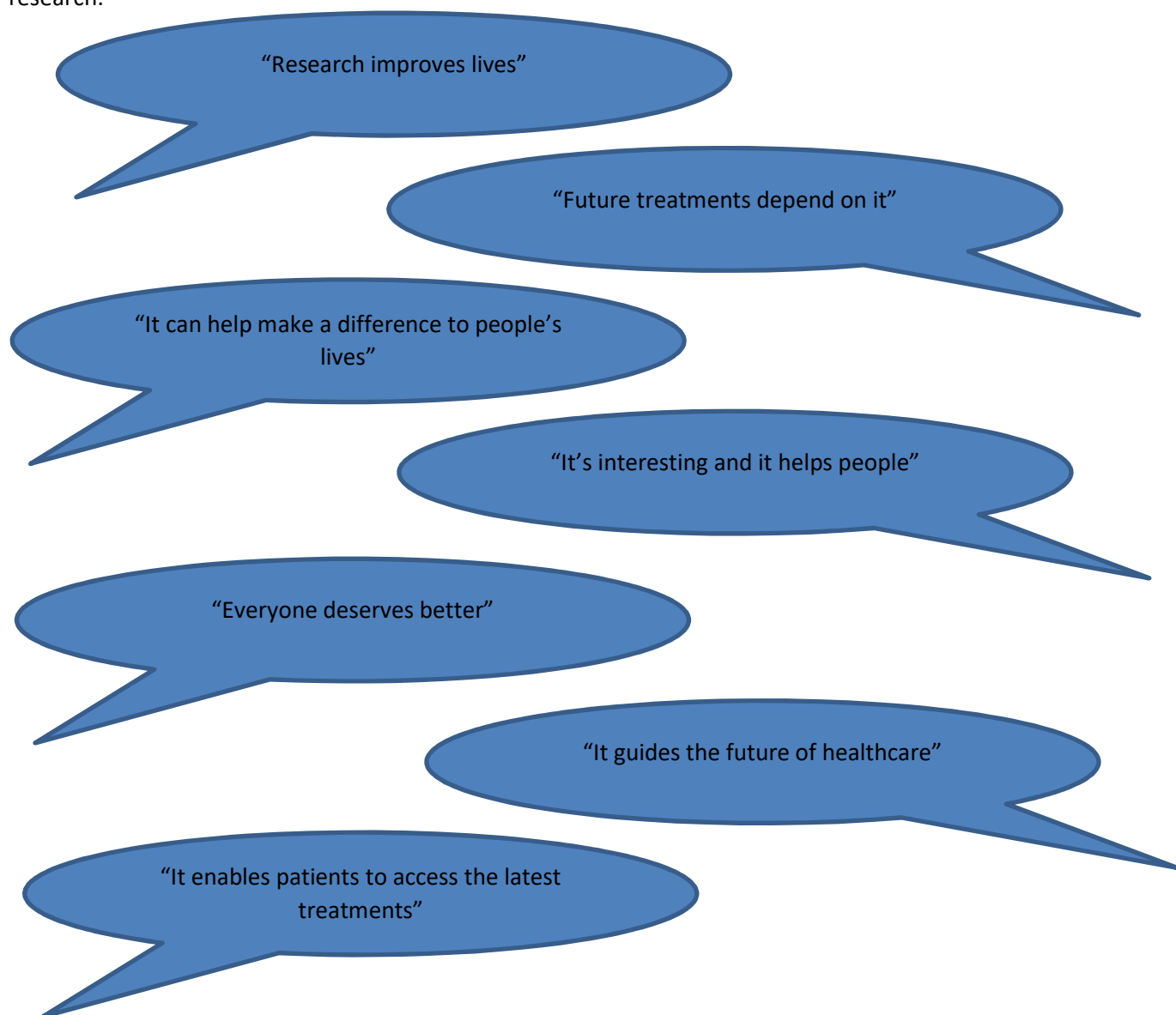
LCRN funded posts wte 18/19
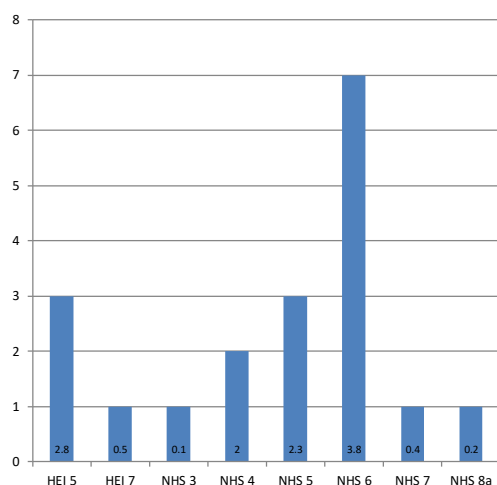
LCRN funded posts wte 19/20
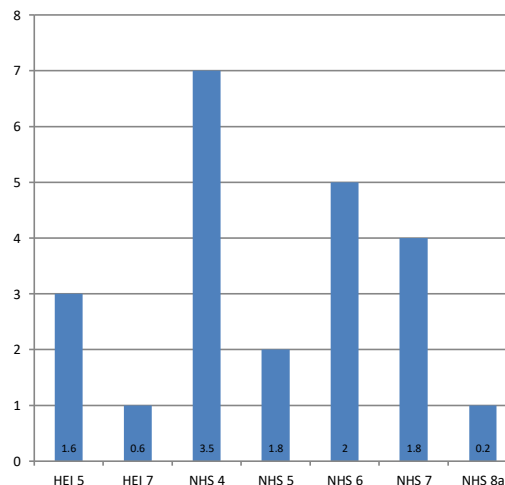
As part of international clinical trials day 2019 R&D staff shared why they want to be part of research:

"Research improves lives"

"Future treatments depend on it"

"It can help make a difference to people's lives"

"It's interesting and it helps people"

"Everyone deserves better"

"It guides the future of healthcare"

"It enables patients to access the latest treatments"

8.2 Research and Development External Funding

Source	2017/18	2018/19	2019/20
NIHR CRN	392,792	400,000	420, 000
CRN contingency funding	12,432	39, 413	5, 000
CRN Greenshoots funding	0	0	13, 358
ETC Funding re qtr 4 2018/19	0	0	3, 106
Research Capability Funding (RCF)	25,016	20,000	20, 000
Commercial Income	13,247	10,453	2, 414
Other Funding			
PoMeT Research project	11,056	0	0
IBER Study	0	5,258	150, 353
STADIA	0	0	7,003
ASCEND	0	0	2,755
Totals	**454,543**	**475,124**	**623,990**

9. Governance- How do we ensure research at BHFT is delivered safely and effectively?

9.1 Overview
Research governance refers to the broad range of regulations, principles and standards of good practice that ensure high quality research. The R&D department is responsible for ensuring BHFT comply with the UK Policy Framework for Health and Social Care Research and related regulations.

9.2 Research Pipeline

| Early Contact | → | Assess, Arrange Confirm | → | Set Up | → | Deliver | → | Communicate Findings |
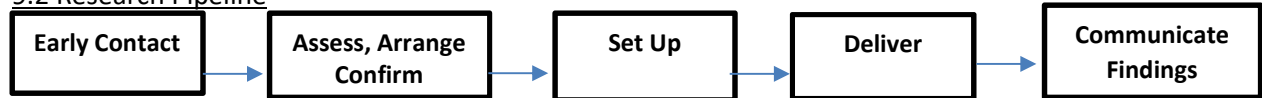
9.3 Research Activity Oversight
The R&D department is responsible for being aware of and registering all research activity that takes place involving BHFT staff, patients, carers or data. In 19/20 we ran a series of communications to ensure that all staff members were aware of this requirement. This included reminders and an open invitation to inform the R&D department about any research that staff may be aware of past, present or future. Communications took place via Trust and local Clinical Effectiveness Groups/Newsletter, Team Brief, Clinical Directors, induction and as part of our attendance at events.

9.4 Standard Operating Procedures and Policies
In 19/20 the R&D department undertook a review of all the existing Research policies and Standard Operating Procedures (SOPS). In line with the UK Policy Framework for Health and Social Care, these;
- Safeguard the participants of research projects
- Protect investigators/researchers by providing a robust and clear framework
- Monitor practice and performance
- Enhance the ethical and scientific quality of research
- Promote good practice and minimise risk

SOP and policy updates which have been implemented so far as a result of the review include a new process for the approval and management of Trust sponsorship for research. This has been designed with Trust Clinicians and University colleagues and features a more robust, structured peer review.

9.5 Data management
Review of processes for capturing/uploading research study information into local research databases was completed to align these to regional systems and to ensure data quality.

9.6 Research passport, honorary research contracts and letters of access
To ensure appropriate access for research purposes to our patients, staff and/or Trust premises, all researchers must have a substantive post with BHFT or be issued with an honorary research contract, or letter of access (LoA) accompanied by a complete Research Passport. In 2019/20 the department issued 54 LoA's to researchers. Local services are involved in these requests.

9.7 Reporting Arrangements
Reporting arrangements include an R&D committee which is chaired by the Head of Research and Development. The R&D Committee met twice in 19/20 and will be relaunched in 20/21. The Medical Director attends as required. R&D report every two months into the Clinical Effectiveness Group.

9.8 Monitoring Arrangements
The R&D department began the development of a comprehensive audit programme at the end of 19/20 to ensure agreed procedures and policies are being followed as part of quality assurance. No Adverse Event or Reactions were reported in 19/20.

10. Performance- How well do we meet our targets and how do we compare to similar Trusts?

10.1 Overview

The R&D Department monitors performance where possible according to three different sets of parameters namely NIHR CRN High Level Objectives, specific BHFT objectives set by the LCRN and internal team objectives which in previous years including 19/20 have generally reflected NIHR and LCRN objectives. We are formally monitored via our LCRN contract on our specific BHFT objectives and we translate these into internal department and individual objectives which we monitor through appraisals. This section of the report notes each set of performance objectives and where relevant our performance. Further performance information follows the objectives tables.

10.2 NIHR CRN High Level Objectives

Objective
1A. Increase the number of research participants
1B: Increase the number of commercial research participants.
2A Increase the proportion of research studies funded by life sciences companies that are delivered in line with the study's planned participant recruitment target and delivery time
2B: Increase the proportion of studies funded by non-commercial organisations that are delivered in line with the study's planned participant recruitment target and delivery time
3A: Increase the number of studies funded by life sciences companies which are supported by the CRN
3B: Increase the proportion of new studies funded by life sciences companies which have received clinical trial authorisation.
HLO 4 and 5 withdrawn. Replaced with new objective HLO 9
6A: Increase the proportion of NHS Trusts which are active in research
6B: Increase the proportion of NHS Trusts which are active in research funded by life sciences companies
6C: Increase the proportion of General Medical Practices active in research
6D: Increase the number of non-NHS sites recruiting research participants
7: Increase the number of participants involved in research into dementias
8: No. of NIHR CRN Portfolio study participants responding to Participant in Research Experience Survey
9A: Reduce the median time it takes to set up research studies funded by life sciences companies by 5%
9B: Reduce the median time it takes to set up research studies funded by non-commercial organisations by 5%

10.3 BHFT specific objectives allocated by LCRN 2019/20

For 2019/20 the LCRN set the following specific objectives for BHFT in line with their Annual Plan:

BHFT specific objective (set by LCRN)	Performance
Overall recruitment target of 1300 (HLO1a)	Exceeded
Support the LCRN communications and engagement team to deliver three press releases about trust research, with patient case study.	All press release requests delivered
Deliver 30 responses to the Patient Research Experience Survey (LCRN)	Exceeded
Submit quarterly financial returns on time (4/4 returns submitted by deadline)	Achieved
Undertake financial controls visit during the financial year	Achieved
Attend monthly LCRN R&D meetings	Achieved
Ensure that 100% of studies upload recruitment promptly to LPMS (Studyline)	Achieved

10.4 The R&D department objectives 2019/20

	Research & Development Objectives for 2019/20			
	Objective	**Measure**	**Target**	**Met?**
1	Deliver significant levels of participation in NIHR CRN Portfolio studies ensuring: • Studies achieve set up time, • Recruit first participant early • Recruit to time and target. • We support at least one commercial trial	Number of participants recruited to NIHR CRN Portfolio studies	1300	1488
		Eligible studies achieving set up within 40 calendar days (from "Date Site Selected" to "Date Site Confirmed")	80%	90%
		Proportion of Commercial/Non-commercial contract studies achieving first participant recruited within 30 days confirmed (from "Date Site Confirmed" to "Date First Participant Recruited")	80%	Yes
		Proportion of commercial/Non-Commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period.	80%	Yes
		Host new Non-CTIMP commercial contract studies	1	No
2	Deliver significant levels of participants recruited into NIHR Portfolio Dementias and Neurodegeneration studies.	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio	TBC	No
3	Promote clinical research across Trust services.	Trust wide research events initiated by the department. The number of new Principal Investigators of NIHR Portfolio studies	5 5	No TBC
4	Patients and Public involvement in research	The number of patients; • responding to patient experience survey • Signing up to Patient Research Ambassadors Program	 50 5	 Yes TBC

**10.5 Additional Performance Information**

10.5.1 Recruitment to NIHR Portfolio Research Projects at Mental Health and Community Trusts-
Top 10 (Graph provided by Clinical Research Network: Thames Valley & South Midlands)
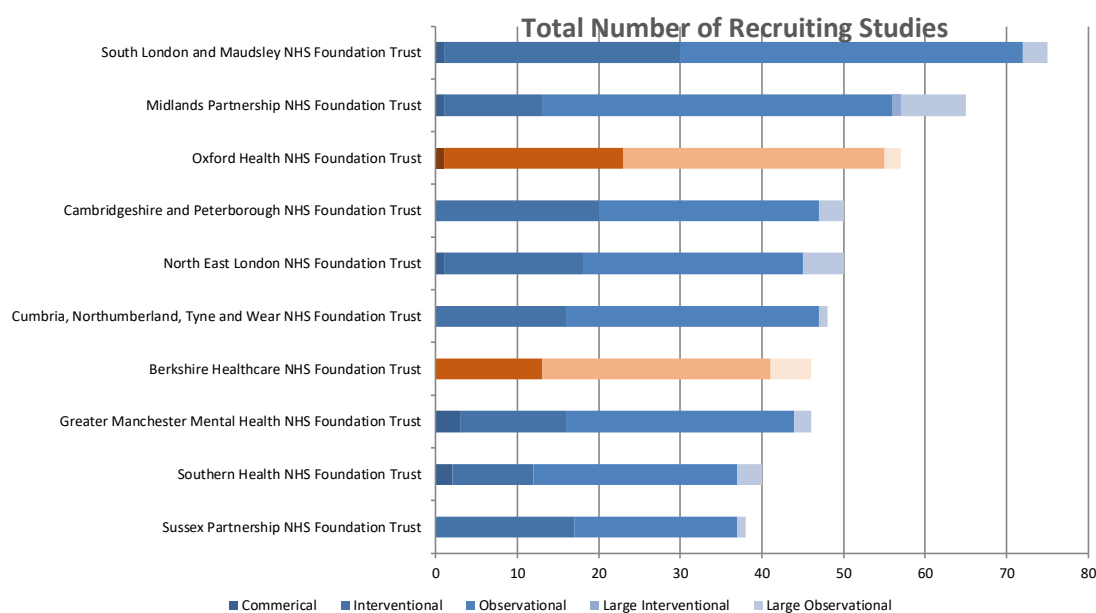
BHFT ranked 7[th] out of 49 benchmarked Trusts in England.

10.5.2. NIHR portfolio set up and recruitment

Our NIHR participant recruitment target was 1300, we exceeded the target by 188 participants due mainly to our dedicated team, new recruitment strategies and recruitment drives, strengthening the leadership team and embedding clinical research practitioners wherever possible in clinical teams. In 2019/20 the highest recruiting study had 214 participants compared to 133 in 2018/19.
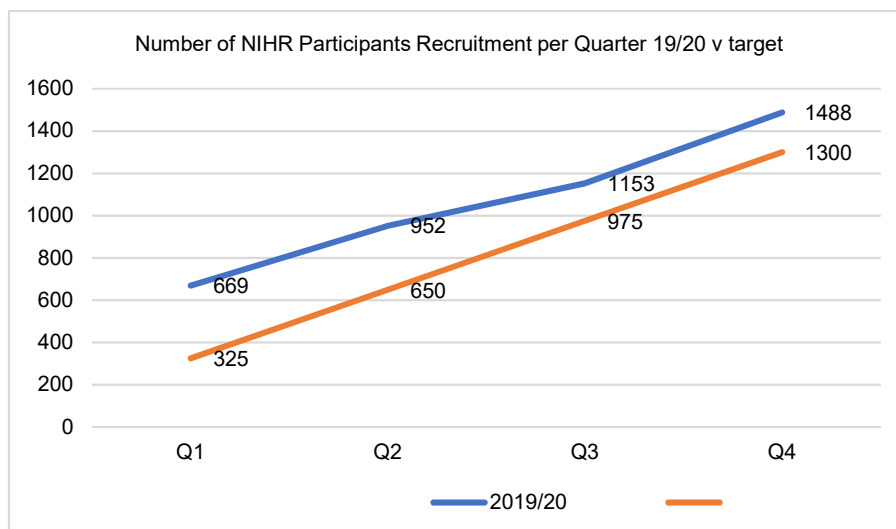
10.5.3 Clinical Trials Performance (CTP)

The Department of Health and Social Care is committed to improving clinical trial performance and reducing site set up and participant recruitment time. To this end NHS providers are required to report delays which have affected or may affect agreed clinical trial study timelines. In particular we are required to publish information on recruitment to clinical trials and delivery to time and to target for commercial clinical trials on our website using a Clinical Trials Performance report.

Eight of the NIHR Portfolio studies that we participated in (see table below) were eligible for the Clinical Trial Performance (CTP) report. To access our 2019/20 CTP reports please visit the link https://www.berkshirehealthcare.nhs.uk/get-involved/our-research-and-development/. Three of these studies did not recruit the first participant in 30 days because no patient consented.

Table show studies that were eligible for the BHFT CTP report.

IRAS Number	Name of Trial
256895	The gameChange Trial: A randomised controlled trial testing automated virtual reality cognitive therapy for patients with fears in everyday social situations
196438	Effective Home Support in Dementia Care: Project 2.1 Dementia Early Stage Cognitive Aids New Trial (DESCANT)
240881	Imagery Based Emotion Regulation for Bipolar Disorder
238744	Early Youth Engagement in first episode psychosis (EYE-2) RCT
258585	Smoking Cessation Intervention for severe Mental Ill Health Trial (SCIMITAR Plus):
254963	Internet-delivered CBT intervention for sleep disorder: a pilot trial
255635	STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties (STADIA)
259611	Re-evaluation of Annual Cytology using HPV testing to Upgrade Prevention (REACH UP): a feasibility study in Women Living with HIV

10.6 Research and Development Annual Report 2018/19

As part of our 2018/19 annual report the R&D department set out a number of activities for completion during the financial year 19/20. The activities together with progress is noted below:

Activity	Progress
R&D Department Baseline Review	Completed October 2019
Research and Development strategy As a minimum a future Trust R&D strategy will need to include:	Postponed until 2020/2021 due to workload
Trust priority alignment- increased research activity aligned to Berkshire Healthcare True North Goals and service specific priorities.	Plan on a page completed in line with True North Goals (see section 12).
Research Development support for locally led research- helping clinicians to receive support to develop, deliver, analyse and write up research ideas as well as apply for research funding.	Review of current demand, capability and required resource is underway.
Research into Practice initiatives- clear mechanisms to feed research results back into the organisation and to implement research findings where clear evidence has been established.	Findings included in R&D annual report. Service specific research reports designed for discussion with clinical services. Showcase event held in Psychological Therapies
Clear roles and integration of Patient and Public in all research activity	PPI plan in development
Equality and Diversity focus- ensuring all services are supported to offer all available research opportunities to all eligible patients and carers, that Berkshire residents receive the same research opportunities as neighbouring counties, including the latest treatments and interventions as part of commercial and non-commercial trials.	See section 6.
Building our commercial research capability and capacity- enabling more patients to receive medications as part of pharmaceutical company sponsored clinical trials.	Links made with regional experts to provide support, training and mentoring for involvement in clinical trials. Clinical Trials Pharmacist appointed begins 20/21.
Establishing sustainable relationships with partners- enhancing the research opportunities available to patient, carers and staff members by partnering with and supporting local academics, industry, voluntary sector and other health and social care organisations.	See section 11.

10.7 CQC Requirements

In September 2018 the CQC signed off the incorporation of clinical research in its Well Led Framework (NHS Trusts). The focus is on how well an NHS Trust as a whole supports research activity at three levels. These are noted below and addressed in numerous sections throughout this report:

Research equity – *how does the organisation support the research programme across the breadth of its services?*

Research facilitation – *how does the organisation proactively support the delivery of research from board level to the clinical setting(s)?*

Research awareness – *how does the organisation make research opportunity known to patients, the public and healthcare professionals?*

11. **Partnerships and Collaborations**

A summary of key partnerships and collaborations together with activities in 2019/20 were as follows:

<u>11.1 NIHR Local Clinical Research Network (LCRN) Thames Valley and South Midlands</u>

The NIHR Clinical Research Network comprises 15 Local Clinical Research Networks that cover England. They coordinate and support the delivery of research in the NHS and wider health and social care landscape. The LCRN that we relate to is Thames Valley and South Midlands which covers Berkshire, Buckinghamshire, Milton Keynes and Oxfordshire.

As discussed earlier in the report the LCRN is our main funder however they also provide networking and training opportunities, expert support, guidance and national and regional updates. As an organisation we attend meetings and contribute to initiatives at Executive, Head of Service, Manager and Lead practitioner/Research Nurse level.

<u>11.2 University of Reading including Thames Valley Clinical Trials Unit</u>

Our main research collaborations with the University of Reading are with the School of Psychology and Clinical Language Sciences. In the last year we have supported academics with developing research proposals, linked academics with clinicians to work on research ideas, funded academics to support the development of key research areas, funded staff to support NIHR portfolio delivery, acted as lead NHS organisation or participating site for University of Reading led NIHR portfolio studies, reviewed the work and function of the Thames Valley Clinical Trials Unit and met regularly with the Heads of School to ensure we are prioritising areas of mutual interest. Masters course information including placement opportunities were also shared by University of Reading colleagues at our recent Psychological Therapies showcase event.

Outside of the School of Psychology and Clinical Language Science we have also supported research projects and/or funding applications with the School of Pharmacy and Department of Food and Nutritional Sciences. We have also met with the Department of Computer Science, Henley Business School- Informatics stream and Biomedical engineering to explore potential opportunities relating to our digital and technological developments as part of the Global Digital Exemplar. These will be further explored in 20/21.

<u>11.3 Oxford Health NHS Foundation Trust</u>

Over the last year BHFT have developed a relationship with its near neighbour Oxford Health. We have reviewed similar objectives and complementary interests and are looking to put ourselves in a position to exploit any joint opportunities. This is at an early stage, but Oxford Health have already presented a number of opportunities for us to act as a Patient Identification Centre (PIC) for some of their research projects. Learning has also been shared around 'consent to contact' for research, the national opt out requirements for research, Information Commissioner Officer visits and sponsorship processes to prevent duplication of effort. A joint meeting was also held to discuss how we might better work with GP's to identify research participants. This collaboration is endorsed by the Thames Valley and South Midlands Clinical Research Network.

<u>11.4 Royal Berkshire Hospitals NHS Foundation Trust</u>

In January 2020 BHFT and RBH met to discuss potential collaboration opportunities. Information regarding department structures and team skill sets were shared. It was felt that collaborations relating to Dementia and Neurodegeneration studies might bring the most benefit to Berkshire

residents as RBH open relatively few NIHR portfolio studies in this specialist area and it is a national priority area. Meanwhile BHFT have expertise in the team to deliver these studies but not necessarily the equipment and medical back up that may be required. We will continue to explore these opportunities later in 20/21.

11.5 Oxford Academic Health Science Network (AHSN)

BHFT are represented on the Oxford AHSN R&D group by the Head of R&D. Chaired by Joe Harrison, Chief Executive of Milton Keynes University Hospital NHS Foundation Trust, and led by Prof Gary Ford, Chief Executive of the Oxford AHSN, the R&D group comprises representatives from universities, NHS trusts and related bodies in the Oxford AHSN region. The group meets approximately three times a year and its remit is to provide opportunities for collaboration between the NHS and university partners within the region in all aspects of R&D impacting on health and healthcare. During 2019 the Oxford AHSN worked with regional research partners to implement the findings of a national survey of local NHS research and innovation needs commissioned by the AHSN Network with the National Institute for Health Research (NIHR) and NHS England.

Benefits of representation at the R&D group include the receipt of key updates for example AHSN programmes, NIHR Applied Research Collaborations, Clinical Trials Unit review and the UK Clinical Research Collaboration.

12. Strategic Alignment- R&D as a core part of the BHFT offer

The R&D Department have been working in 19/20 to further align ourselves with the wider BHFT vision and objectives. In particular we have focussed on the True North Goals. Our plan on a page is presented below. In relation to the BHFT vision one of the ways we can be recognised as a leading mental health and community service provider is by offering opportunities to access the latest treatments and interventions which would not otherwise be available as part of standard care. This can be achieved by participating in national research projects and we benefit free resource to deliver these interventions whilst on trial.

In addition to delivering externally led research projects within BHFT we also support individuals within the organisation to undertake their own research. This is just one 'tool' in a BHFT staff member's toolbox which can assist them to better understand and improve the services that they provide. The other tools are audit, quality improvement and service evaluation:

Research- allows us to drill down into an area which we would like to better understand e.g. why do some groups of the population not access services? Does service model x work better than service model y? Something will usually be classed as research if i) it involves randomising people into different groups, ii) the study protocol requires changes to treatment, care or services from accepted standards or iii) the study is designed to produce generalisable or transferable findings.

Audit- enables us to find out if are we following specific standards set out for us as part of policies and guidelines e.g. NICE guidelines.

Quality Improvement- allows us to make incremental changes to existing processes and services. BHFT has a comprehensive programme of training and support in relation to QI methods and tools.

Service evaluation- enables us to answer the questions- is this service doing what it set out to do?/what standard does this service achieve? It seeks to measure existing services and generally involves some or all of the following: i) staff or patient experience ii) safety iii) effectiveness iv) service utilisation and v) cost benefit.

Team name: Research and Development

TEAMS Plan on a page 2020/21 (Team Objectives)

Our vision: To be recognised as the leading community and mental health service provider by our staff, patients and partners.

True North goal 1: Harm-free care

✓ To provide safe services, prevent self harm and harm to others

We will do this by:

1. Increasing the proportion of research projects which relate to COVID-19 and the reduction of falls, pressure ulcers, self-harm and suicide.
2. Ensuring increased visibility for clinical and service leads of all current research and proposed future research.

True North goal 2: Supporting our staff

✓ To strengthen our highly skilled and engaged workforce and provide a safe working environment

We will do this by:

1. Improving our research development support offering for individuals who would like to develop and/or deliver research studies
2. Better support research career development pathways
3. Increase retention by understanding and better supporting staff wellbeing
4. We will support staff to embed working remotely for a significant part of their role and to develop the necessary skills to operate safely and effectively.

True North goal 3: Good patient experience

✓ To provide good outcomes from treatment and care

We will do this by:

1. Using the patient research experience survey feedback to make necessary improvements to our service including specific engagement on new ways of working where relevant
2. Work with our partners to increase the proportion of interventional v observational research
3. Increasing access to research opportunities in service areas where there are no current active research projects

True North goal 4: Money matters

✓ To deliver services that are efficient and financially sustainable

We will do this by:

1. Reviewing approval, screening and delivery processes to ensure that they are as efficient and effective as possible.
2. Identify an increased number of research projects that focus on technologies which reduce clinical time for BHFT services.
3. Move to electronic systems and eliminate paper where possible.

IMPORTANT: depending on the focus of your team, you may have just one team objective under one True North goal and four or five under another section e.g. most Human Resources Team objectives will relate to True North 2

See reverse for guidance

13. 20/21 Highlights- What has been happening in R&D to date this financial year?

In the first part of 20/21 the R&D department focus has been responding to the impacts of the COVID-19 pandemic on existing research, supporting the wider COVID-19 effort within BHFT and supporting new COVID-19 research. More specifically:

- Adapting to working remotely
- 12 of our existing NIHR portfolio studies were paused due to the in-person delivery method.
- 12 amendments were processed to allow research projects to move from face-to-face delivery to online delivery.
- All staff embedded in clinical services were given permission to use their research funded time for clinical work as required.
- Two staff members were redeployed part time to the staff redeployment bureau.
- Three staff members were redeployed part time to the Royal Berkshire Hospital between April 2020 and June 2020 to support the COVID-19 ISARIC. The aim was to study the COVID-19 disease to better understand its spread and behaviour by analysing biological samples and data from patients with confirmed cases of the disease across the UK. The study team collected samples and data from COVID-19 patients in 166 UK hospitals to answer many urgent questions about the virus in real time. This was Europe's largest analysis of hospitalised patients with COVID-19. BHFT staff supported with the lengthy documentation completion for participants which RBH found it difficult to resource alongside it's numerous other COVID-19 studies.
- The NIHR Clinical Research Network have asked us to prioritise Urgent Public Health studies, followed by other COVID-19 projects. We continually review all projects in these categories and whilst earlier studies were tailored to acute hospitals we are now seeing more that BHFT could potentially take on/be involved with as part of wider collaborations.
- To date we have opened two COVID-19 studies – Psychological Impact of COVID-19 and COVID-19- enforced social isolation and mental health.
- More recently we have also been asked to prioritise the national RESTART initiative which as the name suggest requires us to now restart all paused research and to start any NIHR portfolio project that are in our pipeline but we have delayed starting due to COVID-19.

14. Future Direction- Where next for R&D at BHFT

Over and above the plan on the page that we have developed for 20/21 and COVID-19 requirements we will be working to restart the development of the BHFT R&D strategy. This will include:

- Clarity around the extent to which BHFT wish to engage in **commercial research** and agreed approaches for doing so.
- **Further alignment with service priorities** via plans on a page, QMIS project filters, service plans.
- **Patient and Public Involvement plan** for research linking in with existing groups if possible.
- **People plan** to better support and increase the expertise of R&D funded staff members
- **In-house research support services improved offer** within existing resources and capabilities with a potential investment case outlining what could be achieved with further investment.
- **Exploring the value of the R&D department as a wider research and evidence function** as opposed to a department supporting design and delivery of research only, with a view to further supporting evidence-based decision making across the organisation.
- **Partnership and collaboration plan**- including other neighbouring NHS acute Trusts, NHS mental health Trusts, Universities and the charitable sector.

Summary of All Studies in Berkshire Healthcare FY2019/20 by Condition/Topic Area

Dementia – 2019/20 projects			
Study title and lead	Summary	Reference	Study end date
Alzheimer's Dementia Genetics **(PI- Nick Woodthorpe)**	ADG is a study run by Cardiff University looking for DNA bio-markers specifically related to Alzheimer's disease. This involves a blood test preferably but samples of saliva can be collected where bloods are not available. Cognitive measures, a quality of life questionnaire and family history are collected in addition to the samples. (Study on hold)	2014-31b	31/03/2021
BDR3 **(PI- Gwen Bonner)**	Brains for Dementia Research is a study whereby participants have donated their brains to the research project following their death. In a longitudinal approach participants are reviewed on an annual basis to understand their cognitive function, physical health and other specified markers which are then paired with brain tissue analysis following harvest of the brain.	2018-14	31/03/2021
Dementia with Lewy Bodies Genetic study **(PI- Nick Woodthorpe)**	DLB Genetic study is a study run by Cardiff University looking for DNA bio-markers specifically related to dementia with Lewy bodies. This is a branch of the original Alzheimer's Dementia Genetics study and has the same samples to be collected including blood test (or saliva where this is not possible), cognitive measures, quality of life questionnaire and family history.	2019-05	31/07/2020
Nutrition, hydration and care for people with dementia at the end of life: How can we best support family carers? **(PI- Adebayo Anjorin)**	The aims of this University College London study are to explore carers' understanding of how best to manage eating and drinking at the end of life for someone with dementia; establishing if there are gaps in their knowledge and also identifying what information Practitioners provide to carers. We will set the scene for developing a carer resource if this appears desirable.	2019-20	31/07/2020
Exploring and managing dementia in black African and Caribbean Elders – EMBRACE **(PI- Stephen Zingwe)**	Our Older adult services will collaborate with University College London to conduct a qualitative study with semi-structured interviews and participant observations to explore how people from the UK's Black ethnic groups and their families and friend carers conceptualise and manage memory problems and dementia, their expectations of and attitudes towards treatment and care, and the lived experience of the individuals with dementia who continue to live independently at home or move to a care home, and their family carers. (2019-19)	2019-19	31/05/2021
Living well and enhancing active life: The IDEAL-2 study **(PI- Nick Woodthorpe)**	IDEAL-2 is a longitudinal study utilising questionnaire approach to understand the lived experience of individuals living with dementia and that of their carers. This is a multi-site multi-organisation study that is aiming to build a database of information that can be accessed by researchers in the future. This study is currently in its fourth year coming into the fifth and has produced several research papers from the data collected to date.	2018-17	30/06/2020
PriDem: Primary care led support in dementia: Developing best practice **(PI – Nick Woodthorpe)**	New recommendations have been made about the types of help needed by people with dementia. We want to find out what you think about these recommendations and how to put them into practice. This will help us to develop a new model for support people after a diagnosis of dementia. PriDem are looking to interview you and/or a family member or friend about your experiences. They are looking for people with a diagnosis of any type of dementia. They would also like to talk to family members or friends of people with dementia. You can participate together or separately.	2019-08	03/06/2020
Current practice relating to Assistive Technology within Memory Services **(PI – Gwen Bonner)**	This project aims to determine current practice of professionals working in memory services in the provision of information on, and access to, Assistive Technology for families living with dementia.	2018-28	31/05/2019 On hold

Study title and lead	Summary	Reference	Study end date
IASIS dementia use case (LC – Sarra Blackman)	To obtain confirmatory evidence that the relevance of factors which may be related to the onset, type, clinical phenotype and rate of progression (as measured using serial documentation of MMSE or MoCA scores or other clinical cognitive measures) of neurodegenerative dementia, can be validated and quantified in data stored in electronic clinical records.	2020-01	31/03/2020
Clarity-AD (LC – Sarra Blackman)	This is a multinational, 28pprox.28tre, double-blind, placebo-controlled, parallel-group study using a Bayesian design with response adaptive randomization across placebo or 5 active arms of BAN2401 to determine clinical efficacy and to explore the dose response of BAN2401 using a composite clinical score (ADCOMS)	2019-27	31/03/2021
GRADUATE II (LC – Sarra Blackman)	The purpose of this study is to find out the effects, good or bad, of gantenerumab (new study drug) compared to a placebo (inactive) drug on participants with early Alzheimer's disease (AD) and their memory problems, cognition and day to day functioning.	2019-45	29/02/2020
FREE-COG (PI – Dr Nick Woodthorpe)	To test the Free Combined Cognitive and Functional Assessment (FREE-COG) in naturalistic clinical settings to compare scores with existing, commonly used cognitive tests. We hypothesise that there will be no significant difference between the FREE-COG and these tests.	2018-35	31/08/2019
The cognitive and neurological effects of bilingualism on the progression of dementia (Academic project PhD – Toms Voits)	This study fills an important gap in the literature, by directly addressing claims that bilingualism can provide protection against cognitive decline and brain deterioration in older age.	2018-08	01/01/2020
Better Conversations with Primary Progressive Aphasia (BCPPA) (PI – A Volkmer)	The primary objective of this study is to pilot the BCPPA program with a no treatment group over participating sites to establish for a main trial whether a trial of BCPPA can be delivered as intended in an NHS setting.	2017-26	01/10/2021

Mental Health – 2019/20 projects			
Study title and lead	Summary	Reference	Study end date
ADHD			
PROUD (PI – Dr James Jeffs)	Aims to evaluate the effectiveness of a new intervention to prevent comorbid depression and obesity in ADHD	2017-34	30/07/2020
Anxiety			
Genetic Links to Anxiety and Depression (GLAD) (PI – Dr Amir Zamani)	Kings College London will explore genetic and environmental factors associated with risk for depression and anxiety disorders in the UK, to understand these common disorders and help develop better treatments. The participants will be recruited into an existing biobank, the NIHR BioResource for Translational Research in Common and Rare Diseases, a re-contactable biobank. Our recruitment will help towards forming the largest re-contactable biobank of participants diagnosed with or suffering from two very common disorders, depression and anxiety, who will be primarily recruited through an online platform.	2019-13	01/09/2028

Autism			
Females with Autism Spectrum Disorder and Borderline Personality disorder – the overlap **(PI- Trevor Powell)**	Using Interpretative Phenomenological Analysis, explore and identify themes around how females with both ASD and BPD perceive self-harm, abandonment and their diagnosis, in order to learn more about the overlapping features of ASD and BPD.	2019-17	30/12/2020
Elucidating the relationship and co-development of sensory reactivity and mental health symptoms in autism **(PI -Teresa Tavassoli)**	This project will explore if sensory reactivity, such as being oversensitive to sounds, is associated with anxiety and related mental health symptoms. To do so we will follow 100 3-4 year old autistic children and 100 5-6 year old autistic children for 5 years.	2019-23	01/05/2023
SPRINT: The Prevalence of Social Communication Problems in Adult Psychiatric InpaTients **(PI – Mary Waight)**	Aims: 1) To estimate the prevalence of Autism Spectrum Disorders (ASD's) amongst adults who have been admitted to psychiatric hospitals (including those with intellectual disabilities) population of adult psychiatric inpatients. 2) To examine the association between other mental and physical health conditions in adults who meet diagnostic criteria for ASD's with those who do not meet such criteria (all of whom have been admitted to a psychiatric hospital).	2020-06	01/06/2021
Autism diagnosis as social process an exploration of clinicians' diagnostic decision **(PI – Trevor Powell)**	The aim of the project is to explore the key issues for healthcare professionals in diagnostic decision-making around Autism Spectrum Disorders (ASD). We are interested in healthcare professionals' beliefs, practices and decision-making processes when undertaking ASD assessments in secondary care.	2017-13	31/07/2019
Borderline Personality Disorder			
A questionnaire study examining the link between experiences of betrayal and Borderline Personality Disorder (BPD) **(Clinical Psychology Doctorate – Stephanie Barningham)**	This study will investigate whether experiences of betrayal (betrayal sensitivity and betrayal of others) are a key feature of BPD and will compare betrayal responses across the three groups (BPD, OCD clinical control and non-clinical control group). Student project	2019-30	25/09/2020
Bipolar			
Imagery Based Emotion Regulation (IBER) **(PI – Craig Steel)**	BHFT have collaborated with the University of Reading to do a study to test whether a psychological therapy, called Imagery Based Emotion Regulation (IBER), can help with the symptoms of anxiety within people already diagnosed with bipolar disorder. Recent research suggests that most people diagnosed with bipolar disorder may also suffer from anxiety, but they rarely get assessed, diagnosed or treated for this part of their mental health.	2018-06	30/09/2020

Depression			
Genetic Links to Anxiety and Depression (GLAD) **(PI – Dr Amir Zamani)**	Kings College London will explore genetic and environmental factors associated with risk for depression and anxiety disorders in the UK, to understand these common disorders and help develop better treatments. The participants will be recruited into an existing biobank, the NIHR BioResource for Translational Research in Common and Rare Diseases, a re-contactable biobank. Our recruitment will help towards forming the largest re-contactable biobank of participants diagnosed with or suffering from two very common disorders, depression and anxiety, who will be primarily recruited through an online platform.	2019-13	01/09/2028
Exploring loss of interest and pleasure in depressed adolescents **(Academic Project, PhD – Rebecca Watson)**	This study is looking to understand more about teenagers' experiences of pleasure and enjoyment. This research aims to help us understand depression in young people and how it relates to not enjoying activities and experiences and hopes that it will help develop new and better ways to help young people and to prevent depression.	2018-25	02/09/2019
The Examination of Parent-Adolescent interactions in the treatment of adolescents with depression **(LC – Monika Parkinson)**	The aim of this research is to help us better understand depression in adolescents: Study 1 – To understand the impact of low mood on adolescents' memory and thinking processes. Study 2 – To explore how adolescents and their parents get along and to see if this has an impact on depression treatment success.	2015/52	31/12/2019
Eating Disorders			
TRIANGLE **(PI – Dr Elma Ramly)**	Our Eating Disorder service is collaborating with King's College London on a project involving patients with anorexia nervosa and their carers. The project investigates whether providing extra information on how to cope with the illness to both patients and carers improves their wellbeing up to 18 months post-admission. The aim is to ensure a smooth transition between inpatient treatment and integration in the community. The project also entails measuring symptom burden with questionnaires at different time points. Patients will be reimbursed for completing the questionnaires.	2017-01	30/06/2020
The influence of social communication styles and cognitive profiles on restrictive eating disorders in women **(Academic Project, PhD – Janina Brede)**	This current study aims to assess the role of autism-specific factors for the development and maintenance of restrictive eating disorders (REDs) in autistic individuals, via a comparison of autistic women with AN, women with AN who are not on the autism spectrum, and autistic women who do not have an eating disorder.	2020-02	31/12/2020
An exploration of the relationships between attachment, expressed emotion and early symptom change in family therapy for adolescent anorexia nervosa **(Clinical Psychology Doctorate – Francesca Glover)**	The study is trying to find out more about why family therapy for Anorexia Nervosa might be more helpful for certain people and less helpful for others. In order to investigate this, we are going to use questionnaire measures to explore the effect of two things on the outcome of treatment: 1) Adolescents' emotional bond (or 'attachment') to their main caregiver. 2) The ways in which emotions are communicated ('expressed emotion') between adolescents and their parents.	2020-03	16/04/2021

Psychosis			
THRIVE **(LC- Emma Donaldson)**	A randomised controlled trial comparing Virtual Reality Confidence Building with VR Mental Relaxation for people with fears about others	2018-19	30/09/2020
EYE-2 **(PI – Katherine Mckinnon)**	A randomised controlled trial that aims to evaluate the effectiveness of a team based intervention in Early Intervention Psychosis teams.	2018-31	01/03/2021
Molecular Genetics of Adverse Drug Reactions (MolGen) **(PI- Dr Sharif Ghali)**	A biomarker study that aims to define the genetic and non-genetic risk factors predisposing to adverse drug reactions to clozapine.	2013-04	30/04/2021
PpiP2 **(PI- Dr Sanjoo Chengappa)**	A study that aims to establish the prevalence of pathogenic antibodies in patients with first episode psychosis.	2017-44	01/09/2020
The Game Change Trial **(LC – Emma Donaldson)**	The gameChange Trial: A randomised controlled trial testing automated virtual reality cognitive therapy for patients with fears in everyday social situations.	2019-22	01/06/2021
Exploring Unusual Feelings **(PI – Emma Cernis)**	This study is a questionnaire study where 1000 patients with non-affective psychosis will answer a pack of 10 questionnaires (31pprox.. 30 minutes), and some brief demographic details (age, gender, ethnicity). They will answer the questionnaires once only (a "cross-sectional" design). We will then use the latest statistical methods (network analyses based on probability estimations) to understand the likely causal relationships between the psychological factors measured. Specifically, the aim of the study is to better understand what factors cause dissociation, and whether dissociation might cause psychotic symptoms	2019-32	30/04/2020
Hearing Nasty Voices **(PI – Sanjoo Chengappa)**	The overall purpose of the research is to better understand the problem of hearing derogatory or threatening voices	2020-09	30/09/2020
Improving self-esteem in patients with persecutory delusions **(Clinical Psychology Doctorate – Ava Forkett)**	This study is for people who have concerns that others are trying to harm them. The purpose is to find out whether a talking therapy will help to increase self-compassion and feelings of safety Student project	2018-22	02/03/2020
Does being more satisfied with romantic relationship status increase wellbeing in people who experience psychosis? **(LC – Emma Donaldson)**	Questionnaire study to measure if increased satisfaction with romantic relationship status is associated with better wellbeing outcomes in people who experience psychosis	2020-04	01/09/2020
Attitude to Voices **(LC – Emma Donaldson)**	A limited literature suggests that clinicians can find it difficult to talk to patients about their voice-hearing experiences. These difficulties may reduce the likelihood of patients gaining access to evidence-based treatments. This study aims to explore clinicians' views, attitudes and experiences with regards to working with patients who hear distressing voices.	2019-09	30/09/2019

EMPA Vision (PI – Cathy Darby)	The objective of this trial is to assess the effect of empagliflozin on cardiac physiology and metabolism aiming to provide a scientific explanation of the underlying mechanism by which empagliflozin improves Heart Failure (HF) related outcomes in patients with chronic heart failure.	2018-33	31/08/2019
Model fidelity of Early Intervention services for first-episode Psychosis in England (LC – Emma Donaldson)	A survey that will collect information about how early intervention for psychosis (EIP) services are being delivered across England. This information will be used to describe EIP fidelity nationally (i.e. how closely EIP services across England adhere to the intended EIP model), examine whether EIP services have reduced suicide and hospitalizations in people experiencing early psychosis, and assess whether 'fidelity' to the EIP model of care influences this relationship.	2019-35	07/01/2020
Mental Health Practitioner Survey (LC – Emma Donaldson)	This is a prospective study over 4-6 months. We will be examining behavioural and psychological factors in patients with long-term conditions in primary and secondary care.	2018-37	30/04/2019
Enhancing Future Directed Thinking in People with First Episode Psychosis (Clinical Psychology Doctorate – Kelsey Smith)	**Primary Objective** Does a positive guided imagery intervention increase positive future directed thinking more than a neutral guided imagery intervention? **Secondary Objectives** Is future directed thinking related to levels of negative symptoms in people with first episode psychosis?	2018-26	31/05/2019
AppROVE (LC – Emma Donaldson)	This study aims to evaluate the psychometric properties of two new measures of assertive responding to: 1) distressing voices ('auditory hallucinations'); and 2) other people.	2018-03	31/08/2019
EFFIP (PI – Jacqueline Sin)	Randomised controlled trial commencing with an internal pilot RCT to evaluate the effectiveness of an online intervention to promote carers' wellbeing.	2017-41	31/12/2020
The SlowMo Trial (PI – Gwen Bonner)	This study aims to test the clinical efficacy of SlowMo, a new therapy, and determine the mechanism through which it reduces paranoia severity, over 24 weeks, and to identify participant characteristics that moderate its effectiveness (either by moderating the degree of change in the mechanism, or by influencing adherence to the intervention).	2016-77	01/09/2020
PTSD			
Stop-PTSD (PI – Anke Ehler)	The design is a single blind (assessors of treatment outcome blinded) randomised controlled trial comparing two therapist-assisted internet-based psychological treatments for posttraumatic stress disorder and a wait-list condition, with an embedded process study	2017-39	30/09/2020
Schizophrenia			
Smoking Cessation Intervention for Severe Mental Ill Health Trial (SCIMITAR): Extended follow up. (PI – Sanjoo Chengappa)	To establish the clinical effectiveness of a bespoke smoking cessation intervention compared with usual GP care, for people with severe mental ill health in facilitating smoking cessation.	2019-15	01/03/2020

Suicide			
National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH) **(PI – Louis Appleby)**	Establishing and regulating working practices for safeguarding the receipt, disclosure and holding of identifiable patient information	2018-38	04/01/2022
Qualitative study with Mental Health Practitioners' **(Academic Project, PhD – Zaid Hosany)**	The purpose of this study is to understand the views and preferences of staff working in the CRHTT (Mental Health Practitioners, Senior Mental Health Practitioners, Advanced Mental Health Practitioners, Managers, Psychologists and Assistant Psychologists and Psychiatrists) regarding the use of Brief Suicide-specific Psychological Interventions (BSPI) within a Crisis Resolution and Home Treatment Team (CRHTT) service.	2018-36a	06/01/2021
Quantitative study with Mental Health Practitioners **(Academic Project, PhD – Zaid Hosany)**	The purpose of this study is to evaluate whether a training in brief suicide-specific psychological interventions (BSPI) with Mental Health Practitioners (MHPs) within a Crisis Resolution and Home Treatment Team (CRHTT) service to support suicidal patients produces measurable changes in nursing practice and patient care.	2018-36b	06/01/2021
Suicide by middle aged men **(PI – Louis Appleby)**	This study will combine multiple sources of information to examine factors related to suicide in this hard-to-reach group, including barriers to accessing services.	2019-28	31/10/2020
IAPT (Talking Therapies)			
Understanding SilverCloud Supporter Information Practices & Data Needs **(PI- Sue Scuphum)**	A brief 35 minute interview with Psychological Wellbeing Practitioners, who are currently using the SilverCloud service as 'supporters' to look at their experiences of working with SilverCloud	2019-33	30/06/2020
Internet-delivered CBT intervention (Space for Sleep) for sleep disorder: a pilot trial **(PI – Sarah Sollesse)**	The current study seeks to investigate the feasibility of an internet-delivered CBT-based intervention for sleep disorder. CBT for Insomnia is evidence based and recommended as first line treatment in NICE clinical guidelines in the UK and the evidence based intervention for the management of sleep problems (Schutte-Rodin, et al., 2008). The findings will be used to understand the feasibility of an online intervention for sleep disorder/difficulties and to improve the programme in accordance with user needs.	2019-14	01/07/2020
The Bigger Picture – IAPT **(LC – Grace Jell)**	This project will identify patient groups at risk of disengagement and/or poor outcome. The follow-up project then will purposively select and interview people in (and working with) these groups to identify associated causal mechanisms, including a focus on positive deviance (services performing better than predicted)	2019-38	01/06/2021
Non-specific mental health			
Cause and Prevalence of Memory Problems (CAP-MEM) **(LC- Stephen Zingwe)**	A questionnaire study that aims to explore the cause and prevalence of memory problems in people with mental health, neurodevelopmental and neurodegenerative disorders.	2018-23	30/09/2021

Study title and lead	Summary	Reference	Study end date
Peer Support in Mental Health Services **(Academic Project, PhD – Tishna Uttamlal)**	Aims: 1) To understand the identity of a PSW and how this is constructed. 2) To examine how and why PSWs may construct or be implicated in a liminal space based on their identity construction. 3) Use this to understand organisationally, how PSWs fit into the current workforce and make recommendations for future steps in developing and sustaining the PSW role. 4) To see what factors contribute to the notion of liminality in peer support workers 5) Which of these are seen as positive and which of these are seen as negative and how this influences a PSWs identity	2019-41	01/09/2021
ESCAPE – Views about smoking cessation and mental health **(LC – Emma Donaldson)**	This study is inviting health care professionals working with patients with mental health difficulties in *any* context to take part in an online survey to help us understand current attitudes, practices, training needs, and perceived barriers and facilitators to address and implement smoking cessation treatments.	2020-15	TBC

Children and Young People (CYP) – 2019/20 projects			
Study title and lead	Summary	Reference	Study end date
STAndardised Diagnostic Assessment for children and adolescents with emotional difficulties (STADIA): **(PI- Tamsin Marshall)**	Population: Children and young people (age 5-17 years) presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS). The aim of the study is to evaluate the clinical and cost effectiveness of a standardised diagnostic assessment (SDA) tool as an adjunct to usual clinical care in children and adolescents presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS).	2018-20b	30/04/2022
Parents' experiences of parenting a child with Obsessive Compulsive Symptoms/Disorder **(Academic Project, PhD – Chloe Chessell)**	This study aims to explore parents' experiences of parenting a child (aged 7 to 12 years) with OCD, their views and preferences towards different levels of parent involvement in CBT for OCD. Student project	2019-07	29/08/2020
Treatment of Panic Disorder in Adolescents (PANDA Study) **(PI – Polly Waite)**	A research project to compare two talking therapies, that involve working with a therapist one-to-one, for the treatment of panic disorder in young people aged 11-17½ years	2019-34	30/09/2021
Nursing-led Interventions to support the psychological and emotional wellbeing of children and young people **(LC – Emma Donaldson)**	The study has been established to explore, across the four countries of the UK, nurse led interventions for young people's mental health and wellbeing.	2019-40	14/09/2019

Physical Health Service – 2019/20 projects			
Study title and lead	Summary	Reference	Study end date
All Long-Term Conditions (LTC)			
Psychological risk factors for fatigue in Rheumatoid Arthritis **(PI – Cathy Beresford)**	The study investigates a number of factors which may influence levels of fatigue, distress and disability in patients with long-term conditions. It specifically focusses on behavioural and psychological factors including quality of sleep, anxiety and depression, beliefs about fatigue and coping strategies.	2018-37	01/04/2021
Sexual Health Services			
PrEP Impact Trial Study **(PI – Dr Nisha Pal)**	The PrEP Impact Trial aims to address outstanding questions about PrEP, eligibility, uptake and duration of use of PrEP though expanding the assessment to the scale required to obtain sufficient data. In addition the trial will assess under real world conditions the impact of PrEP on new HIV diagnoses and on sexually transmitted infections, compared to historical controls.	2017-30	01/09/2020
Re-Evaluation of Annual Cytology using HPV testing to Upgrade Prevention (REACH UP): a feasibility study in Women Living With HIV **(PI – Nisha Pal)**	To estimate HPV prevalence in women living with HIV to calculate sample size of the main study	2019-16	31/01/2021
Safetxt **(PI – Nisha Pal)**	Safetxt will reliably demonstrate the effects of the intervention on STIs at one year. The effects of the intervention on partner notification, condom use and STI testing will be reported. Understanding which intervention components (behaviour change techniques) are effective could generate principles to inform the content of future interventions. Which interventions are effective will be explored by collecting data on the theoretical constructs influenced by the intervention components and on the pathway to behaviour change.	2016-40	30/08/2019
Diabetes service			
Startright (Getting the right classification and treatment from diagnosis in adults with diabetes) **(PI- Dr Mohammadi Alizera)**	Our Diabetes at King Edwards VII are teaming up with University of Exeter Medical school to support recruitment into this study aiming to achieve more accurate early classification of diabetes and identification of which patients will rapidly require insulin treatment. The clinicians will record clinical features and biomarkers that may help to determine diabetes type at diagnosis and follow participants for 3 years to assess the development of severe insulin deficiency (measured using C-peptide) and insulin requirement. Findings will be integrated into a freely available clinical prediction model.	2018-02	30/06/2020
Embedding Diabetes Education RCT **(PI- Alison Marie Jones)**	As part of the Embedding Diabetes Education study (an NIHR funded PgfAR) Leicester diabetes centre are going to be working with the Diabetes Education provider team at Berkshire Healthcare NHS Foundation Trust to assess whether the embedding Package reduces HbA1C in patients with type 2 Diabetes Mellitus compared to usual care	2019-04	31/01/2021
Exploring patient and healthcare-professional perspectives on barriers and facilitators towards foot self-care practices in diabetes (Academic Project, PhD – Andrew Hill)	This study primarily seeks to explore patient and healthcare-professional perspectives on perceived barriers and facilitators to foot self-care practices in diabetes. In addition, this study will explore whether similarities and/or differences between patient and healthcare-professional perspectives in this context contribute to these barriers and/or facilitators	2020-08	31/12/2021

Cardiac and Respiratory Specialist Services (CARSS)			
TANDEM (Tailored intervention for Anxiety and Depression Management in COPD) **(PI- Katherine Beckford)**	Our Cardiac and Respiratory Specialist Service is collaborating with Queen Mary University of London Research study for patients with Chronic Obstructive Pulmonary Disease (COPD); also known as chronic bronchitis or emphysema. To investigate the benefits of offering people with moderate to very severe Chronic Obstructive Pulmonary Disease (COPD) and mild or moderate anxiety or depression, the opportunity to receive structured, one to one support and advice delivered by a trained respiratory health care professional (nurse, physio or occupational therapist). The sessions are based on a Cognitive Behavioural approach. COPD can affect many aspects of such patients; breathing difficulties can limit their day-to-day activities and can make them feel worried (anxious) or feel low (depressed).	2018-29	30/06/2021
Brain Injury			
The influence of changes in self-concept after brain injury **(Clinical Psychology Doctorate – Christina Cusack)**	Aims and Objectives of the study: 1. Is carer burden influenced by brain injury survivors' perceptions of self-concept? 2. Is carer burden influenced by their perceptions of changes in self-concept of the brain injury survivor? 3. Is perceived social support influenced by brain injury survivors' and relatives' perceptions of self-concept changes in the brain injury survivor? Are the factorial and psychometric properties of the HISD-III-R equivalent to those of the patient's version of the HISD-III? (exploratory)	2019-10	01/05/2020
Dental			
(Dental Caries Study) Public Health England Dental Public Health Dental Epidemiology Programme survey of five-year-old children 2018/19 **(LC – Stephen Zingwe)**	The aim of the survey is to measure the prevalence and severity of dental caries among 5-year-old children within each lower-tier local authority. The resulting reports give details of caries levels and other clinical measures and provide information for local authorities, the NHS and other partners.	2020-13	30/06/2019
Digestion			
Assessing the ecological role of yeast in the gut **(Academic Project, PhD – Grace Ward)**	This study will analyse the biological and chemical content of the samples. We will analyse the stool samples provided by you, to capture information on the composition of microorganisms present in the gut. The samples will also be analysed using analytical chemistry approaches to study the metabolic activity of the microorganisms.	2019-24	30/09/2021
Pregnancy			
Patients perceptions of perinatal mental health services in Berkshire **(PI – Amir Zamani)**	This study seeks to explore the perinatal service user's perspective regarding the perinatal mental health services within the Berkshire locality	2018-13	30/09/2019

Non-health related studies – 2019/20 projects			
Study title and lead	Summary	Reference	Study end date
Data			
CLIMB: University of Cambridge NHS/HSC Health Data Consent Survey **(LC – Sarra Blackman)**	To establish patient and public views on the sharing of identified NHS/HSC health data (for clinical purposes) and de-identified health data (for research) within the UK.	2020-10	30/06/2020
Infrastructuring Data Integration between Multiple Socio-Technical Contexts of Care **(Academic Project, PhD – Andrey Elizondo)**	How is the integration of data across care settings negotiated between different actors? What –intended and unintended- early consequences arise as a result of data integration? Student project	2019-29	30/04/2020
EMHEP 3: Efficiency, cost and quality of mental healthcare provision **(LC – Emma Donaldson)**	This research will analyse the efficiency, cost and quality of mental healthcare provision in the English NHS.	2020-05	30/04/2021
Culture			
Culture and difference within the supervisory relationship. **(Clinical Psychology Doctorate – Charlotte McCann)**	How are issues of culture and difference in clinical psychology training and practice perceived and explored within the supervisory relationship?	2019-39	01/10/2020
The lived experiences of career progression of NHS BME Very/Senior Managers/Executives in South West of England and Greater London **(Academic Project, PhD – Stephen Zingwe)**	The researcher wishes to examine the experiences of career progression of NHS BME staff working in senior/very senior management positions that are in the South West of England Region and Greater London.	2020-12	31/01/2021
Does feeling connected and valued affect the way people feel about themselves and their lives in people aged 50 years and older from different cultures **(Clinical Psychology Doctorate – Iman Hassan)**	The study aims to see if feeling connected and valued affect the way people feel about themselves and their lives in people aged 50 years old and above. We are particularly interested in thoughts related to suicide. We are also interested in seeing if there are any differences in people from cultures that place more importance on being part of a group, such as a close family or community network, compared to people from cultures that place more emphasis on the individual.	2019-31	31/07/2020

Appendix 2- Academic institutions and NHS Trusts we have worked with to deliver research in the last four years

Academic Institution (N.B. Name of institution at the time of collaboration)

Aston University	University of Edinburgh
Brunel University London	University of Exeter
Buckinghamshire New University	University of Greenwich
Cardiff University	University of Leeds
Edge Hill University	University of Leicester
Imperial College London	University of Lincoln
King's College London	University of Liverpool
Lancaster University	University of Northampton
McGill University, Canada	University of Oxford
London School of Hygiene & Tropical Medicine	University of Reading
Oxford Brookes University	University of Sheffield
University of Plymouth	University of Surrey
Queen Mary, University of London	University of Sussex
Royal Holloway, University of London	University of Warwick
Sheffield Hallam University	University of West London
St George's, University of London	University of York
Trinity College Dublin	University of Newcastle
University of Manchester	University of Nottingham
University of Bath	London Metropolitan University
University of Bristol	University of East Anglia
University of Cambridge	

NHS Trusts (N.B. Name of Trust at time of collaboration)

Cambridgeshire & Peterborough NHS Foundation Trust	Southern Health NHS Foundation Trust
East Kent Hospitals University NHS Foundation Trust	Sussex Community NHS Foundation Trust
Greater Manchester Mental Health NHS Foundation Trust	Sussex Partnership NHS Foundation Trust
Imperial Healthcare NHS Trust	University College London Hospitals NHS Foundation Trust
King's College Hospital NHS Foundation Trust	Chelsea and Westminster Hospital NHS Foundation Trust
South London and Maudsley NHS Foundation Trust	Guy's and St Thomas' NHS Foundation Trust
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	Leeds Teaching Hospitals NHS Foundation Trust
Northumberland, Tyne and Wear NHS Foundation Trust	NHS Greater Glasgow and Clyde
Nottinghamshire Healthcare NHS Foundation Trust	Royal Free London NHS Foundation Trust
Oxford Health NHS Foundation Trust	Royal Devon and Exeter NHS Foundation Trust

Appendix 3- List of Staff Publications

ALLEN, C. & LI, I. 2019. The path from individual therapy to co-production and community-based projects. *Psychology of Older People: The FPOP Bulletin*, 41-46.

ANDREWS, J. A., BROWN, L. J., HAWLEY, M. S. & *ASTELL, A. J.* 2019. Older Adults' Perspectives on Using Digital Technology to Maintain Good Mental Health: Interactive Group Study. *Journal Of Medical Internet Research,* 21, e11694-e11694.

ASTELL, A.J. & DOVE, E. 2019. The Kinect Project: Group motion-based gaming for people living with dementia. *Dementia (14713012),* 18, 2189-2205.

ASTELL, A.J., SMITH, S. K. & JODDRELL, P. 2019. *Using Technology in Dementia Care : a guide to technology solutions for everyday living*, Jessica Kingsley. 9781785924170

ASTELL, A. J. 2019. Creating technology with people who have dementia. *In:* SAYAGO, S. (ed.) *Perspectives on human-computer interaction research with older people.* New York: Springer. 9783030060756

ASTELL, A. J., BOURANIS, N., HOEY, J., LINDAUER, A., MIHAILIDIS, A., NUGENT, C. & ROBILLARD, J. M. 2019. Technology and Dementia: The Future is Now. *Dementia And Geriatric Cognitive Disorders,* 47, 131-139.

ASTELL, A. J., DOVE, E. & HERNANDEZ, A. M. 2019. Brief history of technology for dementia. *In:* ASTELL, A. J., SMITH, S. K. & JODDRELL, P. M. (eds.) *Using Technology in Dementia Care: A Guide to Technology Solutions for Everyday Living.* London: Jessica Kingsley Publishers. 9781785924170.

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Appendix 4- Example Service Level Research Report (currently NIHR portfolio studies only) for discussion and sharing with relevant clinical services

Children and Young People (CYP) sample research report (NIHR portfolio)

Past

Studies in last 5 years (with same breakdowns as earlier)

Study	Study Summary	Year(s) Active
A-CAT	The study aimed to inform the development of targeted interventions designed to improve rates of access to treatment for child anxiety disorders	November 2016 to 31/07/2018
N-CAT National Survey	The study aimed to improve access to treatment for children with anxiety disorders in England	June 2016 to 31/07/2017
Development of an online treatment programme for child anxiety	This study aimed to (i) design and develop an online and smartphone application treatment programme for childhood anxiety disorders and (ii) test the usability of the online tool to ensure that it is easy to use and appealing to those who it is aimed at (i.e. parents, children and clinicians)	24/10/2016 to 31/07/2017
Understanding what maintains social anxiety disorder in children	The overall aim of the study was to understand what psychological mechanisms maintain social anxiety in children	25/11/2016 to 03/09/2018
PTSD in childhood: A clinician survey	This study aimed to systematically examine and synthesise relevant quantitative, qualitative and mixed-method literature relating to clinicians' perceived barriers and facilitators to the implementation of evidence-informed interventions at all levels of the system for individuals with PTSD	09/04/2018 to 27/09/2018
Psychological treatment of panic disorder in adolescence: the view of CAMHS clinicians	The aim of this study was to establish what training National Health Service (NHS) Child and Adolescent Mental Health Services (CAMHS) clinicians have received in psychological therapies and panic disorder and how they identify and treat panic disorder in adolescents	01/04/2018 to 31/12/2018
Cost of Autism	The study aimed to find out the amount of clinician time it takes to assess a child for possible Autistic Spectrum Disorder (ASD) and from this calculate the resulting costs to the NHS	19/06/2018 to 31/08/2018

Present

Studies in 19/20

Study	Study Summary
STADIA	The aim of the study is to evaluate the clinical and cost effectiveness of a standardised diagnostic assessment (SDA) tool as an adjunct to usual clinical care in children and adolescents presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS)
PANDA	The study aims to extend previous research by evaluating the brief form of cognitive therapy developed by Clark et al. (1999) with adolescents with panic disorder

Future

Studies in 20/21

- STADIA
- PANDA

Accepted studies (either just started recruitment or currently in set up):

Study	Study Summary
ASCEND	The aim is to carry out a feasibility study which will inform a future pilot/full trial to test whether an intervention focussing on early social communication skills is effective in improving language skills before children with Down syndrome start school.
MAPS	The study aims to develop a set of music-assisted intervention programmes to increase spoken language ability in 24-60-month-old, nonverbal or minimally verbal children with autism spectrum disorder (ASD)
P-TAC	This study aims to determine the feasibility of a definitive RCT comparing Online Support Intervention to face-to-face parent-guided treatment for children with anxiety disorders
IVY	The aim of this study is to establish the effectiveness and cost-effectiveness of Intensive Community Care Services compared with Usual Inpatient Care, Treatment As Usual (TAU) in young people with severe psychiatric disorders

Potential Studies (still undergoing feasibility assessment):

Study	Study Summary
Early evaluation of the Children and Young People's Mental Health Trailblazer programme	The study aims to examine the development, implementation and early progress of the trailblazer programme. The evaluation will explore how service delivery models and implementation strategies differ across trailblazer areas, highlighting factors (e.g. local contexts) that are promoting or hindering progress towards programme goals, and drawing out the practical implications of the findings for the development of the programme and the longer-term evaluation
Online PTSD Treatment for Young People and Carers	The study aims to evaluate an Internet-delivered Cognitive Therapy (iCT) programme for the treatment of PTSD in adolescents
Olfaction in adolescent-onset psychosis study	The study aims to examine the brain mechanisms underlying olfaction in those with adolescent-onset schizophrenia (AOS), compared to healthy adolescent controls
Using virtual reality to test fears among adolescents with social anxiety disorder: A multiple case series	The study aims to assess whether young people experience performance fears and associated negative cognitions in virtual reality social scenarios

Impacts

The CYP service has supported 9 portfolio studies over the past 5 years.

PTSD in childhood: a clinician survey identified four barriers related to supporting this patient population, these barriers were inflexibility of manualised approaches, a fear of increasing client distress, working with comorbidities and a lack of training and support. The most dominant theme within clinician related barriers was a lack of training, which further linked to a number of other clinician barriers identified including an uncertainty of how to approach trauma, a lack of knowledge, and a lack of confidence in using evidence-informed interventions. Future research is needed to explore the nature of the training and supervision needed by clinicians.

The psychological treatment of panic disorder in adolescence: the view of CAMHS clinicians study found that only half of CAMHS clinicians identified panic disorder from a vignette and although CBT treatments are widely offered, only a minority of adolescents with panic disorder are receiving treatments developed for and evaluated with young people with panic disorder. The researchers

concluded that there is a vital need for clinician training, the use of tools that aid identification and the implementation of evidence-based treatments within CAMHS.

Other studies that have recruited from within CAMHS services have highlighted the need and guidance on identifying child anxiety difficulties and ensuring sufficient provision is available to allow families to access support promptly.

The studies have enabled families to have a voice and comment on the services provided, they have been able to help identify what helps them to access support and what the barriers are when trying to access services. The research has provided them with the opportunity to contribute to service changes and improvements. The studies have provided further understanding regarding the treatments available, knowledge and skill set of clinicians and effectiveness of current treatments. The studies have also helped to inform the development of new treatments and interventions for the patient population. These studies have helped to inform future research to improve treatments and service provision which will help to improve outcomes for this patient population.

Equity of access

No information regarding equity of access due to the fact patients have either been recruited via online methods or directly from the AnDY clinic or CAMHS service.

Talking Therapies sample research report (NIHR portfolio)

Past

Studies in last 5 years (with same breakdowns as earlier)

Study	Study Summary	Year(s) Active
E-COMPARED	The study aimed to gain knowledge on the clinical and cost-effectiveness of blended depression treatment compared to treatment-as-usual in routine care	05/09/2016 to 31/03/2017
DIGITAL IAPT	The study aimed to evaluate the immediate and longer-term impact, as well as the cost effectiveness of internet-delivered interventions for depression and anxiety	22/06/2017 to 30/04/2018
A survey of mindfulness and self-compassion in IAPT	The study aimed to test if people with clinically significant OCD symptoms showed disproportionately poor mindfulness and self-compassion skills when compared to non-OCD clinical controls and to healthy controls	31/07/2017 to 31/03/2018

Present

Studies in 19/20

Study	Study Summary
STOP PTSD	The study aims to compare a trauma-focused (internet-delivered Cognitive Therapy for PTSD, iCT-PTSD) and a non-trauma focused therapist-assisted online psychological therapy (internet-based stress management therapy, iStress-PTSD)
Understanding the information practices and data needs	The study aims to identify suitable data methods, including innovative machine learning approaches, to better understand: (1) how users of an online mental healthcare intervention (SilverCloud Health) are making use of this service; and (2) how such insight can be leveraged to improve that service
The Bigger Picture	The study aims to investigate the impact of neighbourhood deprivation on IAPT (Improving Access to Psychological Therapies) service outcomes

Studies in 20/21
- STOP PTSD
- Understanding the information practices and data needs
- The Bigger Picture

Accepted studies (either just started recruitment or currently in set up):

Study	Study Summary
Precision in Psychiatry Study (PIPS)	The study aims to develop a tool that can be used by doctors to improve their ability to identify the best treatment for each unique person - helping people get better, faster

Potential Studies (still undergoing feasibility assessment):

Study	Study Summary
The Implementation of Digital Interventions in Healthcare Services	The study aims to explore stakeholder experiences (mental healthcare workers, patients, intervention developers) of the implementation of an internet-delivered intervention in NHS IAPT Services
Integration of a smartwatch within an internet-delivered intervention for depression: a randomized trial on feasibility, satisfaction and acceptance	The study aims to examine the feasibility and acceptance of using a smartwatch to monitor patients' mood, sleep and physical activity in order to support an internet-delivered CBT based Intervention
The PROMISE Study Version 1	The study aims to see which components of the two psychological models can predict participant engagement with Headspace

Impacts

The Talking Therapies service has supported 6 portfolio studies over the past 5 years.

A survey of mindfulness and self-compassion in IAPT study found that participants with clinically significant obsessive-compulsive disorder symptoms reported lower trait mindfulness and self-compassion compared to participants with clinically significant anxiety/depression and to non-clinical controls.

The E-Compared study found that patients showed a significant decrease in depressive symptoms when treated via E-COMPARED's blended cognitive behavioural therapy compared to control groups undergoing regular therapy sessions. Participants valued the easy-to-use interface and the use of digital tools. Therapists also welcomed the technology, they felt it provided them greater insights into patients' symptoms and enabled them to treat patients more effectively. The data generated by the digital tools can enable researchers to improve and personalise treatment approaches for depression. Researchers hope that it may predict which patient groups would benefit most from internet-based, standard or blended treatment by modelling patient characteristics.

Both studies contribute to understanding and as a result will enable review of current treatments and development of new treatments. The findings will also help to inform potential future treatments and interventions for this patient population. The Talking Therapies service has welcomed online treatments and are currently working with Silvercloud to continue to increase the number of online interventions we can offer to patients.

Equity of access

No information regarding equity of access due to the fact patients have been recruited via online methods.

Eating Disorders sample research report (NIHR portfolio)

Past

Studies in last 5 years (with same breakdowns as earlier)

Study	Study Aim
SHARED	The study explored the efficacy of adding a guided self-help intervention (*Recovery* MANTRA) to treatment as usual for anorexia nervosa

Present

Studies in 19/20

Study	Study Aim
TRIANGLE	Aims to examine whether the addition of a patient and carer skill sharing intervention improves long-term patient wellbeing following hospital treatment for anorexia nervosa

Future

Studies in 20/21

- Triangle

Potential Studies (still undergoing feasibility assessment):

- DAISIES Trial

Impacts

The Eating Disorders service have supported 2 portfolio studies over the past 5 years.

The SHARED study found that augmenting outpatient treatment for adult anorexia nervosa with a focus on recovery and motivation produced short-term reductions in anxiety and increased confidence to change and therapeutic alliance.

The SHARED study provides a greater understanding regarding online treatments for anorexia nervosa and how these can help improve outcomes. The study enabled Berkshire Healthcare patients to access a new intervention to help support their recovery and was positively received by the service. The SHARED study was important in assessing whether this kind of treatment is feasible within Eating Disorder services and has led onto other studies looking at online treatments for anorexia nervosa. Overall the SHARED study will contribute to overall understanding about online interventions and how these can be implemented in practice as standard.

Equity of access

100% of patients screened were female

90% of patients were White British and 10% were from other ethnic backgrounds

36% of patients were from West Berkshire, 27% were from Reading, 19% were from Wokingham, 9% were from Bracknell and 9% were from WAM. No one took part from Slough locality.

55% were aged between 18-25, 9% were aged between 26-35, 18% were aged between 36-45 and 18% were aged between 46-55.

Liaison and Diversion sample research report (NIHR portfolio)

Past

Studies in last 5 years (with same breakdowns as earlier)

Study	Study Aim
Outcome Evaluation of Offender Liaison and Diversion Trial Schemes	The study aimed to evaluate the implementation of the national model for liaison and diversion services in ten sites across the U.K.
Improving Healthcare for Probationers: Mapping the Landscape	The study examined how healthcare is provided for people under probation supervision in the community, what research suggests about good practice for improving the health of people under probation supervision, and what mechanisms can be used to measure and facilitate improvements in the quality of healthcare provision for this population

Studies in 19/20

No studies recruited from Liaison and Diversion services in 2019/20.

Future

Studies in 20/21

There are currently no studies going through feasibility, but a search will take place to find out if there are any studies that Berkshire Healthcare could potentially support.

Impacts

The Liaison and Diversion service have supported 2 portfolio studies over the past 5 years.

The Outcome Evaluation of Offender Liaison and Diversion Trial Schemes study found that stakeholders from partner agencies and those delivering Liaison and Diversion services were overwhelmingly positive about the National Model. It was perceived to have resulted in an increase in useful information about vulnerabilities being provided to decision-makers in the criminal justice system and closer working between mental health, and other professionals, and the police and courts. There is some evidence that the National Model may have decreased remand to custody from court slightly, at least in some areas, but this needs to be explored further.

The Improving Healthcare for Probationers: Mapping the Landscape study concluded that the key to improving healthcare for people in contact with probation lies in four main areas; commissioning, policy, practice and research. The researchers designed a toolkit for commissioners and practitioners. This toolkit aims to raise awareness of probationers' likely health needs, what is known about the most effective ways of providing healthcare, models of good practice, and how barriers to providing good quality and accessible healthcare for probationers can be overcome.

Both of these studies improve our understanding and will inform and enable further development of clear pathways, support mechanisms and service provision for this patient population. These studies may enable greater understanding of interventions and treatments needed in order to improve the outcomes.

Equity of access

No information regarding equity of access due to no active studies in 2019/20 and the sensitivity of this patient group.