

Appendix 1 – Study Protocol

Title: IMpLementation of A Relatives' Toolkit (IMPART study): Examining the critical success factors, barriers and facilitators to implementation of an online supported self-management intervention in the NHS

2. Summary of Research

An iterative case study design, conducted across six NHS Trusts, will identify the critical success factors, barriers and facilitators to implementation of an online supported self-management intervention in the NHS. The Relatives' Education And Coping Toolkit (REACT) is an evidence-based online supported self-management intervention for relatives of people with recent onset psychosis, which has been shown to significantly reduce distress and increase perceived ability to cope (22). The intervention was co-produced with relatives, is recovery focussed (www.IMROC.org), and offers an effective way for mental health services across the UK to meet the new 2014 NICE Guideline for psychosis recommendation to provide an education and support programme to relatives. Trusts offering REACT to relatives are also provided with an online REACT Training Package for the supporting staff which provides them with clear guidance and materials to support relatives to use REACT. Previous NICE guidelines (2009) have recommended that relatives are supported through structured Family Intervention. However, NHS Trust surveys estimate that only 1 – 17% of families have received this (4-6). It is therefore vital that the 2014 guidelines are more successfully implemented. Supported self-management interventions, delivered using interactive technology, supported by clinical staff, are becoming an increasingly popular way to deliver cost effective healthcare to people with chronic needs (28, 29) but implementation of these approaches in routine clinical practice is poorly understood. This study will produce a national Implementation Plan for REACT, but the relevance of the findings more broadly will also be articulated to inform wider implementation of self-management interventions in health services.

Our research employs a theory driven case study design (30). This will allow us to understand the process of implementation of REACT within a real-world setting, and to identify the causal factors which determine how well this process works (or not). Based on this approach, we will first introduce REACT to all Trusts during phase 1. All trusts will be provided with a preliminary Implementation Plan (IP version 1) which will include a presentation about the rationale for REACT and clear guidelines on how it should be used by staff. This timing is to coincide with the start of the evaluation of access and waiting times guideline that EI teams in NHS Trusts will be required to follow <http://www.england.nhs.uk/wp-content/uploads/2015/02/mh-access-wait-time-guid.pdf>. It is important that Trusts have a plan in place to meet the target to deliver NICE Concordant care – including information and support to carers by April 2016. (Phase 1, 1-6 mos). Alongside this we will outline an implementation theory about the factors we think will influence successful implementation of REACT, and generate hypotheses about the mechanisms by which they will lead to successful outcome. To do this we will conduct: (1) a systematic review of relevant implementation studies of NHS based interventions to ensure we build on previous knowledge; (2) analysis of data relevant to implementation from the feasibility trial; (3) stakeholder workshops across all participating Trusts; (4) a synthesis of this data informed by our clinical and theoretical expertise in this area. This learning will also inform the items for a Fidelity Scale which will be used by within individual Trusts to assess the extent to which the key components of the Implementation Plan are being delivered. The Fidelity Scale design and development is informed by previous research evaluating implementation of Evidence Based Practice (31). We will then test and refine these hypotheses using an iterative comparative case study design across 6 NHS Trusts (Phase 2, 7-24 mos). Data will be collected from multiple sources and analysed initially within each Trust. Finally (Phase 3, 25-30 mos), we will synthesise data across all Trusts to develop a national Implementation Plan for REACT. We will draw out broader conclusions which can be used to inform implementation of other supported self-management interventions across the NHS, and inform the further evolution of implementation theories.

Our implementation theory is informed by Normalisation Process Theory (NPT) This theory has been successfully used in a wide range of NHS implementation studies and provides a practical framework to guide data collection (www.normalizationprocess.org/). NPT facilitates generation of specific hypotheses about the process by which a

complex healthcare intervention is implemented, embedded and integrated (or not), that can be tested empirically, and has previously been applied in ehealth settings (Murray et al 2011).

Success of implementation will be assessed by the uptake and use of REACT by relatives at each Trust. We will also evaluate the impact of REACT on relatives' distress and wellbeing to test Trust specific effectiveness, and the resources required for implementation at each Trust.

The study will be conducted across 2 geographical sites (North and South of England), with 3 Trusts at each site that will be purposively sampled. This will increase theoretical generalisability of findings across NHS Trusts, whilst allowing research staff employed at each site to manage data collection across Trusts. Detailed case study data will be collected and analysed in two NHS Trusts participating in wave 1 (1 in the North and 1 in the South) to identify the key barriers and facilitators to implementation using IPv1. This analysis will be used to develop a revised Implementation Plan (version 2), and a refinement of our implementation hypotheses. These hypotheses will then be tested using the revised IP which will be introduced to a second Trust at each site (wave 2). Data collection and analysis across these two Trusts will then focus on further hypothesis testing, following which a further iteration of the Implementation Plan will be developed (version 3). This will be introduced to the final Trusts (wave 3), and data from these Trusts, will inform the final draft.

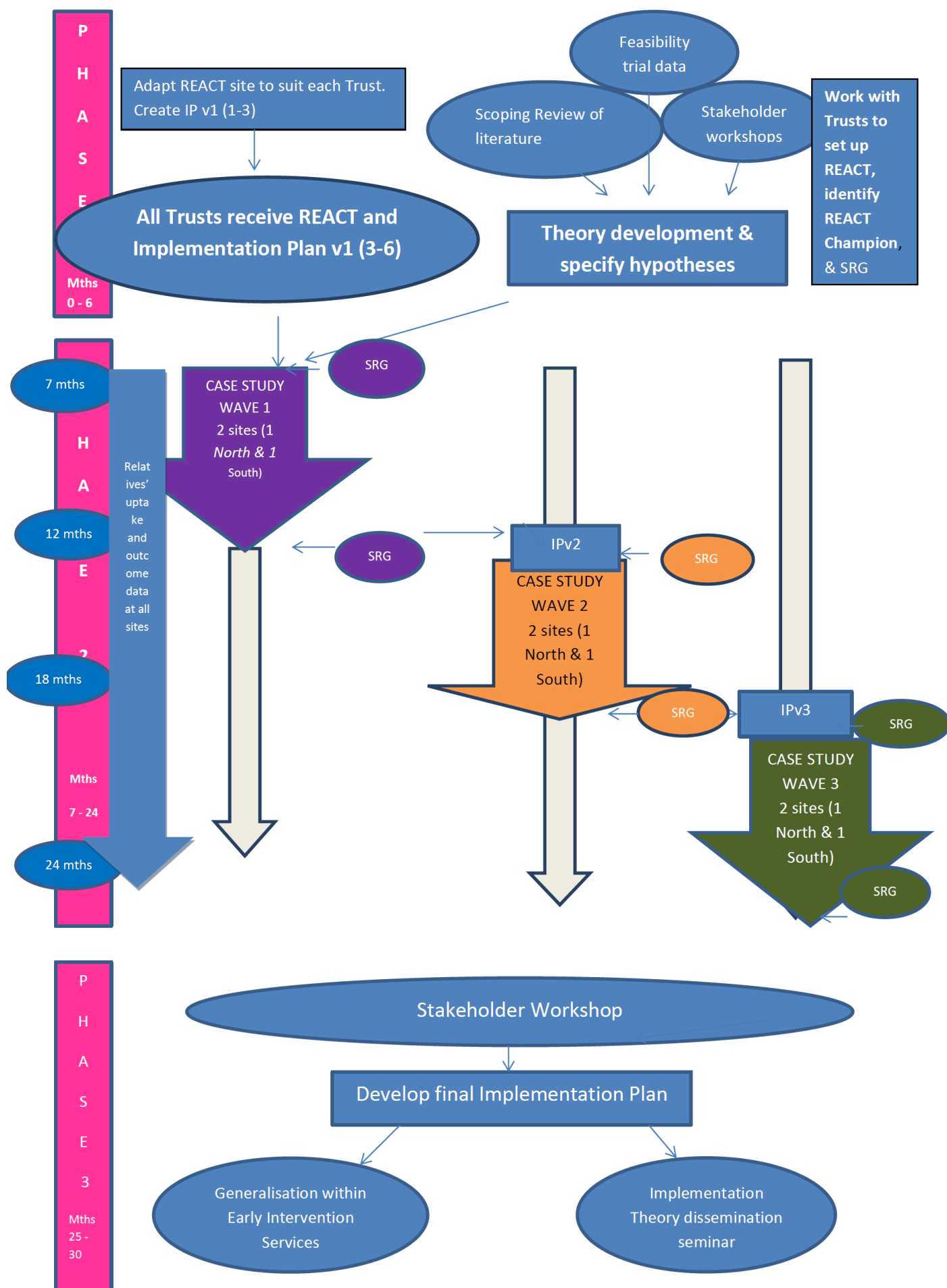
This design means that

- 1- We ensure that all Trusts receive access to the intervention within the timeframe required by NHS England monitoring of access and waiting times.
2. We can capitalise on the valuable opportunity to specifically explore the impact of a significant contextual change (introduction of this monitored standard on access and waiting times) on support for carers – and specifically also on implementation of a digital intervention to support relatives (REACT). Variation between sites will provide important data on factors which influence implementation.
3. We can identify factors that impact on implementation at all stages including initial implementation, embedding and integration.

This design is informed by our clinical experience that implementation can be delayed in NHS settings for many reasons, and therefore it is important that we collect data at both the start of the implementation process, but also continue to see what factors influence whether the intervention is successfully retained and becomes integrated into routine clinical practice in the longer term.

Data sources at each Trust will include observation of naturally occurring meetings, document analysis, Stakeholder reference group focus groups and stakeholder in depth interviews and focus groups. Data will be analysed first within each Trust, providing useful data to participating Trusts to inform future service development plans. In Phase 3 we will synthesise data across Trusts to develop the national Implementation Plan. Analysis and synthesis will be done with input from the entire project team, including Stakeholder References Groups (SRGs) at each site to ensure a co-produced plan with shared ownership.

The exact nature of the Implementation Plan cannot be determined at this stage but will include: a video rationale for the use of REACT including research and policy context; a step-by-step guide to successful implementation of REACT; a Fidelity Scale to enable Trusts to self-monitor fidelity to the Implementation Plan; online REACT supporter training toolkit; a summary of resources needed to implement REACT; measures/evaluation tools to evaluate uptake and outcome for relatives; case examples describing the process of implementation across participating Trusts – where the focus is on identifying and overcoming key barriers. Wider applicability will be tested in a larger conference / workshop with stakeholders from none participating Trusts who will be presented the data and invited to further contribute to the development of the plan and broader implementation theory.



3. Background and Rationale

This research addresses the problem that relatives of people with psychosis are not currently receiving the support and information they need, despite the existence of evidence based interventions (2) and the fact that supporting relatives is an explicitly stated government policy recommendation (8) and a key recommendation of the NICE Guideline for psychosis and schizophrenia (33). Relatives provide the vast majority of care, saving the NHS an estimated £1.24bn per year in the UK (34), but this caring role is associated with high levels of distress in relatives (35, 36), significant practical, financial and emotional burden (37), stigma, worry, shame and guilt (38), trauma (39), and loss (40, 41). Despite the clear need for support, research shows that delivery of recommended interventions to relatives by the NHS is very poor (4-6). A better understanding of the barriers to supporting relatives is vital. This study aims to address this problem by conducting a detailed investigation of the process of implementing a supported self-management intervention which has already been demonstrated to be effective in improving outcomes for relatives of people with psychosis. Identification of the factors which support successful implementation of REACT across multiple NHS Trusts creates new knowledge which is directly relevant to NHS Trusts in complying with NICE Guidelines, and has the potential to lead to changes in practice which can have a direct positive impact on all relatives of people with psychosis (approximately 620,000 relatives) in NHS services across the UK. The findings from this study will also inform improved implementation of other supported self-management interventions across the NHS, and contribute to the growing literature identifying ways to overcome the significant barriers to the translation of research findings into clinical practice. A lot of money is spent on developing and testing new health technologies, but there is conversely very little understanding of how they are successfully implemented in routine clinical practice (1). This study fits the HS&DR remit to produce evidence regarding the quality, accessibility and organisation of health services.

4. Evidence explaining why research is needed now

There is an urgent need for this research as although evidence based interventions for relatives exist, and NICE Guidelines state that relatives of people with psychosis should be supported, relatives' access to interventions is limited and inadequate. A Cochrane systematic review (2) demonstrates the efficacy of family interventions in improving outcomes for people with psychosis, and a further recent systematic review (3) has demonstrated that family interventions can also improve outcomes for relatives. However, audits of NHS Trusts indicate that the majority of relatives do not access family interventions (5). The recent Schizophrenia Commission report (42), summarises the inadequacies in the provision of NHS care for families of people with psychosis, and makes the key recommendation that improving support for relatives and involving them as partners in care should be a national priority. To facilitate implementation of NICE guidelines, the new "Guidance to support the introduction of access and waiting times standards for mental health services in 2015/2016" commits NHS Trusts to ensuring more than 50 per cent of patients experiencing their first episode of psychosis will, from 1 April 2016, access NICE concordant care within two weeks of referral. The impact of this is yet to be seen, but will be assessed within our study design. Throughout the NHS there is a growing interest in the development of self-management approaches as a clinical and cost effective way to deliver healthcare. However, there is also recognition of the urgent need to understand how new interventions are implemented in clinical services (43). Without this, there is a danger that money is wasted on developing new technologies which are never successfully implemented and the gap between evidence and practice becomes ever wider. NIHR has funded the development and evaluation of REACT (PB-PG-0807-14075) which can be made available nationally. To ensure it makes a real difference to people, we now need to understand how this intervention can be successfully implemented in clinical services. This study will specifically inform a national Implementation Plan for REACT, but will also offer a basis for understanding more broadly the factors impacting on implementation of supported self-management interventions across the NHS – especially those delivered online. Recent plans to extend the national IAPT Program (Increasing Access to Psychological Therapies) in England to severe mental illness has led to a scoping exercise to identify evidence based, structured, interventions such as REACT. Understanding facilitators and barriers to the implementation of these will be crucial in determining the successful rollout of such national programs.

5. Aim

The study aims to understand the critical success factors, facilitators, barriers, and resources needed to integrate an online supported self-management intervention for relatives of people with recent onset psychosis into routine clinical care, and to use this information to develop a national Implementation Plan. Findings from this study will also be used to develop the growing evidence base investigating the translation of research findings into clinical practice, particularly regarding supported self-management interventions in mental health.

Objectives

Objectives are to:

- (i) Measure the uptake and use of REACT by NHS EIS teams and relatives.
- (ii) Identify the critical success factors, facilitators and barriers to implementation of REACT.
- (iii) Identify the resources (and costs) needed for successful implementation of REACT in EIS teams.
- (iv) Investigate the impact of REACT on self-reported relatives' outcomes.
- (v) Develop a user friendly REACT Implementation Plan and related resources (inc Fidelity Scale) to facilitate widespread use and dissemination within the NHS.
- (vi) Use the findings from this study to further develop theories of implementation of supported self-management interventions in the NHS

6. Research Plan

6.1 Design and theoretical / conceptual framework

REACT intervention

The REACT intervention was designed to meet the needs of relatives and close friends of people with psychosis. REACT consists of an online toolkit with support to use the toolkit offered by a supporter in the EIS using telephone or email. The development of the REACT intervention was informed by (i) a systematic review of interventions reporting on outcomes for relatives of people with psychosis (3); (ii) a series of focus groups with relatives, co-facilitated by a relative (44); (iii) clinical and personal expertise within the research team (consisting of relatives, clinicians, and academics); and (iv) extensive feedback from service users and relatives throughout the development process. The toolkit is comprehensive and modular in format so that the content is divided into manageable sections which can be used flexibly depending on the individual needs of the relative. These include: Introduction to REACT; What is Psychosis?; Managing Positive Symptoms; Managing Negative Symptoms; Dealing with Crises; Dealing with Difficult Behaviour; Managing Stress – Thinking Differently; Managing Stress – Doing Things Differently; Understanding Mental Health Services (how to get the help you need); Treatment Options; The Future; Resource Directory; Jargon Buster. Modules range in length between the equivalent of eleven and twenty-three A5 pages, though the Resource Directory is considerably longer at forty-three pages. The Resource Directory can be edited to include relevant local resources as well as those available nationally.

Although the information is about people with psychosis in general, the toolkit is designed to help relatives to make this information specific to their family by identifying key questions they may need to ask to get the information they require. Case examples are used extensively to aid illustration. The content of the toolkit reflects the key ingredients in existing evidence based family interventions. All relatives are given a code to allow them to access the REACT site.

Each participant is supported in the use of the toolkit by a trained member of the clinical team. Trusts can identify the most appropriate supporters, given their staff resources and structure. However, we have designed the support to be offered by a non-professional support worker (or equivalent e.g. Assistant Psychologist/Graduate Mental Health Worker) currently working in an EIS team. They are well placed to offer the level of support required for this self-management approach as it does not require highly trained health professionals, but does require availability and flexibility. Importantly, they are also relatively inexpensive thereby avoiding cost barriers to further dissemination. Support workers (also referred to as STR workers – as they offer Support, spend Time with service users and promote Recovery) generally work alongside Care Coordinators to offer practical support to ongoing psychosocial interventions. They primarily work with people experiencing psychosis (rather than relatives). They are generally not trained health professionals but require an interest in working with people with mental health problems, and an ability to demonstrate good basic listening and communication skills. They will have attended mandatory Trust training. They will be also trained to use REACT using standardised training materials provided by the research team. In the initial Implementation Plan (v1) these materials will include an outline of the background and rationale for REACT, and clear guidance on how to use the toolkit. These materials will be developed further in each subsequent iteration of the Implementation Plan, in response to learning about what facilitates implementation. The training recommends that relatives are offered an initial session in which they are introduced to the toolkit (either face to face or over the telephone). Support is then offered by email or telephone or direct messaging through the website (Trusts can decide which form of communication they can best support and whether they can offer relatives a choice) for a maximum of 1 hour per week over 6 months (though in the pilot the median total minutes of support per relative over the 6 months was 125 (IQR = 75-204). To ensure communication is maintained, supporters are asked to contact relatives monthly as a minimum if relatives do not respond to appointments or initiate any contact. Support is targeted at helping relatives to identify the key difficulties they face and guiding them to find the most relevant information and strategies in the toolkit. Discussion then focuses on making these general principles as directly relevant as possible to each individual relative, and helping relatives to try out new strategies and reflect on the impact of these. The toolkit and the support are designed to make the intervention enactive rather than symbolic i.e. it encourages relatives to actively practice new skills, rather than just providing information. The training builds on existing clinical skills of the support workers and focuses on the key areas of motivation to engage with the toolkit, active listening and empathy, identification of key problem areas, and how to support relatives to use the toolkit to best meet their specific needs. REACT was very well received in the pilot study (qualitative and quantitative data) and in response to specific feedback, we have included video clips of relatives sharing their experiences, updated information in the resource directory, and increased the interactivity of the website throughout. We now wish to examine how this intervention can be successfully implemented into routine clinical services.

Theoretical framework

There are many theories relevant to implementation of research into practice. The use of theory is important in helping to generate hypotheses based on the theory about what might be important mechanisms underlying the implementation process. This allows us to structure our data collection framework to test these theories, rather than collecting masses of data with no clear focus. It also ensures that learning from this project is generalised to a broader understanding of implementation science through development of the theory. However, we are keen that our theory should be used as a guide and will not blind us to ignoring other important processes that are apparent through either our feasibility data, or in our data collection at each NHS Trusts. There are several models, frameworks, and theories we could have used to guide our work. We originally proposed the PARIHS framework which has been widely applied in health care settings. However, whilst PARIHS identifies key determinants which act as barriers and facilitators to implementation (specifically evidence, context, and facilitation), and is based on extensive testing and development in healthcare settings, the framework does not offer a theory about the how change happens, or causal mechanisms underlying the implementation process. Nor has it been applied specifically to the adoption of ehealth interventions. We are interested in both of these, and so have chosen to use Normalisation Process Theory (NPT) as our theoretical guide. NPT began as a model (NPM) of the factors that promote or inhibit the routine work of embedding a new health technology into practice. The key constructs identified were: interactional workability; relational integration; skill-set workability; and contextual integration. The model has since been developed into a theory which includes the NPM as

constituting “collective action” and adds concepts of “coherence” (how actors make sense of a set of practices); “cognitive participation” (the means by which they participate in them); and “reflexive monitoring” (how these practice are then appraised). The theory facilitates generation of specific hypotheses about the process by which a complex healthcare intervention is implemented, embedded and integrated (or not), that can be tested empirically, and has previously been applied in ehealth settings (Murray et al 2011). Thus it can act as a guide to focus our data collection and hypothesis testing, whilst also allowing us to develop the theory in light of our findings. Alongside Prof Rycroft-Malone, who is a national expert in implementation science, our team also includes Professor Elizabeth Murray who has worked extensively to develop NPT and its application to ehealth interventions.

Design

Our research employs a theory driven multiple case study design (30). This will allow us to understand the process of implementation of REACT within a real-world setting, and to identify the causal factors which determine how well this process work. Based on this approach, we will first outline a programme theory about the factors we think will influence successful implementation of REACT. This will be based on NPT and facilitated by tools available on the NPT website which can guide this process (www.normalizationprocess.org/). We will generate hypotheses about the mechanisms that will lead to successful outcome, and we will then test and refine these hypotheses using an iterative case study design. Case studies can provide rich detailed data, and are particularly useful when trying to understand the implementation of a complex intervention in a real life setting in which the process cannot be controlled. REACT is a “complex intervention” (47) because it depends on the actions of individuals, across a range of different contexts, and adapting their behaviour over time. It also produces multiple outcomes which need to be understood. Implementation is made more complex by the context in which the intervention is situated, which is dynamic and includes competing demands on the system. A mixed methods approach including quantitative assessments of outcome (delivery and use of REACT), and qualitative assessments of mechanisms including observation, document analysis and in-depth interviews **and focus groups** is therefore required to attempt to capture and make sense of this complexity. We have also designed the study to have extensive input from stakeholder groups at each of the participating Trusts to ensure that the Implementation Plan is truly co-produced and reflects the needs of the stakeholders.

Phase 1 –We will develop our theory of implementation of REACT and generate specific hypotheses based on this. The theory will be informed by Normalisation Process Theory. Specific hypotheses will be informed by:

1. A systematic review of relevant implementation studies to ensure we build on previous knowledge. The exact focus will be determined by a scoping exercise but our focus will be on implementation of new interventions specifically within community mental healthcare settings. The review will begin in phase 1 with a scoping exercise to allow the literature to inform our study early on. However, given the scale of work, the full review will be ongoing throughout phase 2.
2. Analysis of data collected during the feasibility trial which was conducted across 3 NHS Trusts in the North West of England. Data collection in the trial did not focus specifically on implementation issues, but REACT was supported in the study by staff already working within the EIS teams, and detailed supervision notes were made. Many of the issues arising in supervision pertained to implementation issues which offer important insights relevant to developing our implementation theory including: clarity of the REACT supporter role; integration of this role into existing workload; understanding of REACT across other team workers; organisational support for REACT in terms of time allowed for training and delivery. This data will be reviewed to identify factors relevant to successful implementation
3. Stakeholder workshops within and across Trusts. These workshops will serve 3 functions
 - a. Develop good working relationships with key stakeholders at each Trust including commissioners, service managers, clinical staff, service users and relatives. This group will form a Stakeholder Reference Group (SRG) at each Trust.
 - b. Finalise an initial plan (version 1) to facilitate the implementation of REACT, including the rationale and process of integrating REACT into the existing service, and the resources needed to do this. This will include design of a Fidelity Scale to assess fidelity to the Implementation Plan

- c. Generate hypotheses about what the stakeholders believe will be the key facilitators and barriers to the implementation of REACT.

During Phase 1 we will also provide all Trusts with the REACT site and a basic implementation plan (version 1).

Phase 2 –We will use an iterative case study design to collect and analyse data to test our hypotheses about what factors will influence implementation of REACT.

1. Detailed case study data will be collected and analysed to test our implementation hypotheses at the first 2 Trusts in wave 1 for the first six months. During this time, the data will be used to develop a revised Implementation Plan and Fidelity Scale (version 2), and to refine our implementation hypotheses.
2. The revised Implementation Plan (IPv2) will then be introduced to a second Trust at each site (wave 2), and further data will be collected here to test the impact of this and to identify additional factors which are impacting on the longer term embedding of the intervention. Data collection and analysis across both of these Trusts will then focus on further hypothesis testing, following which a further iteration of the Implementation Plan will be developed (IPv3).
3. Version 3 of the Implementation Plan will be introduced to the final Trusts at each site (wave 3), and data from this wave, combined with longitudinal data from the ongoing four Trusts from wave 1 and wave 2 will inform the final draft.

It is difficult to anticipate in advance the ideal number of iterations to develop an Implementation Plan, but we have proposed 3 waves, providing in-depth data from 6 NHS Trusts as our research experience suggests this will provide sufficient depth of understanding across a range of different settings, whilst ensuring the data collection and analysis is manageable within the timeframe and resources requested for the study.

The Implementation Plan will include a Fidelity Scale. This will be developed as part of the iterative case study process. Consistent with previous guidance (31), the scale items will reflect the key principles underlying REACT and procedures identified for successful implementation (identified during phase 1&2). Items are rated on a 1-5 scale from no adherence to full adherence, and average score computed. The measure will be used during the study to identify the extent to which each component of the intervention is being successfully implemented within each participating Trust, and direct data collection. The scale will be developed iteratively during the study as additional key components are identified and areas of poor implementation are investigated.

The final version of the Fidelity Scale will be included in the Implementation Plan and will allow Trusts to self-monitor adherence to the key principles and practices of REACT which have been identified as crucial for successful implementation and outlined in detail in the Implementation Plan. Research has shown this process of self-monitoring can facilitate sustained use of a new intervention (31).

An important consideration throughout the study is the need to clearly record and interpret the role of the research team in the process of implementation. Our aim is to move from a very basic Implementation Plan (version 1) which is informed by our theory about what is likely to influence the implementation process, to a more sophisticated national Implementation Plan at the end of the study which addresses the barriers identified during the study. We acknowledge the problems inherent in the research team both evaluating and also being part of the implementation process, but we believe that without this involvement, it would not be possible to understand the implementation process in the depth and detail needed for this case study design. We will ensure that our data collection is transparent and clear records are kept of what the actions of the research team in facilitating implementation so that this can be incorporated into the analysis. In repeatedly taking the data back to the broader SRGs at each site, and at key points throughout the study, we will ensure sufficient critical distance on our interpretation of all of the data, including our own role in the implementation process.

Phase 3 –We will develop the final Implementation Plan, assess wider applicability for other supported self-management interventions in the NHS, and draw out implications for further development of implementation theory.

1. Data will be analysed in a series of stages to inform the final Implementation Plan.

- a. Within each Trust, data will first be analysed within data set (meetings, documents, interviews or focus groups), and then synthesised across these data sources. The initial analysis will be done at a coding level by the researcher, with input from the research team to identify key themes and to develop the analysis framework.
 - b. Within each Trust these frameworks will be presented in a workshop setting to the SRG within the Trust who will input into a synthesis of data across the data sources, and to draw out the key recommendations from the data that can be used to inform the Implementation Plan.
 - c. In the final stage, data will be synthesised across Trusts. This will be done by inviting members of the participating Trust SRGs to a central meeting at which the key themes across all the data sources at each of the Trusts will be presented. A similar process of discussion will focus around identifying the key recommendations for a national Implementation Plan which will highlight common implementation factors likely to be relevant to all Trusts, but also variability, and include recommendations of ways in which implementation of REACT can be adapted to suit the specific needs of the Trust.
2. Generalisability of the findings will be explored in two ways:
- a. Stakeholders from EIS teams in non-participating Trusts will be invited to attend a workshop in which they will be presented with the REACT intervention, and the final Implementation Plan. This workshop will be co-delivered by the research team and members of the participating Trust SRGs. Presentations will include the research data, and case examples from participating Trusts. Attendees will be encouraged to use the knowledge and experience of the facilitators to develop a plan for how they can implement REACT in their individual Trust. They will be encouraged to ask questions and explore the hurdles experienced at participating sites, and find out how these were overcome.
 - b. We are also interested in the broader relevance of these findings for implementation of other supported self-management interventions in mental health services. There is a rapid increase in the development of such approaches, but to date, no attempt to address the implementation challenges. We will organise a second dissemination event in which the audience will be stakeholders from mental health services (not restricted to EIS teams), and academics and clinicians interested in implementation science. We will present the study findings, drawing out broader implications for other self-management interventions, and for implementation theory. Output will be written up for peer review publications.

6.2 Sampling

Sampling is important at two levels in this project: Trusts; and data sources within each Trust. A framework at each level is based on theoretical sampling i.e. what sample do we need to ensure we get the data required to test our hypotheses. A formal statistical power calculation is not appropriate for this design, but careful sampling will provide sufficient variability to ensure a widely applicable Implementation Plan.

a. Trusts

Purposive sampling of Trusts will ensure variation across key factors including geographic location (North/South), and population (urban/suburban/rural; social deprivation; ethnic diversity). Our participating Trusts consist of varying numbers of EIS teams, with different organisational structures. These are likely to impact on the process of implementation (e.g. supporting relatives with culturally diverse models of psychosis) so it is important that our Implementation Plan is designed to accommodate this variation. We have identified 6 eligible Trusts, 3 in the North of England, and 3 in London/South which we feel best capture this variation. Additional teams have expressed an interest and are reserve options at this stage. Feasibility data provides an estimated population of 150-200 new relatives referred to each Trust per annum. Our implementation period covers 18 months in 6 Trusts giving a total study population of approximately 1350-1800 relatives.

b. Data sources within each site

Data sources will include observation of naturally occurring meetings, document analysis, Stakeholder reference group focus groups and in-depth interviews with stakeholders. The selection of data sources will be informed by the specific hypotheses being tested i.e. we will seek out data which is best placed to help us test our hypotheses. We will ensure that data is sampled from across different levels of the organisations including (a) strategic planning, (b) management and delivery, (c) service users & relatives. Meetings and documents that directly relate to REACT, or to aspects of the service relevant to supporting relatives will be targeted. Where hypotheses suggest particular factors such as staffing levels, or availability of supervision, are important, then meetings and documents that are likely to pertain to these factors will also be analysed. The SRG at each site will help to determine the meetings and documents most relevant at each stage. Examples of relevant meetings are likely to include Trust Board meetings; Adult Mental Health Quality and Performance Meetings; CQUIN target strategy; EIS business and clinical meetings; Carer's Strategy meetings; PPI strategy meetings. Relevant documents are likely to include Trust Annual Quality Accounts; Psychosis Pathway; EIS Commissioning Spec and Operational Policy; CQUIN reports, Carers Strategy, Trust website and service user information leaflets; Complaints and SUI investigations; Service user and carer feedback.

In-depth interviews will also inform our analysis. Based on past experience we anticipate conducting approximately 20 interviews at each Trust with key people from relevant stakeholder groups including service commissioners, service managers, supporters, relatives and service users. **Relatives will be offered the opportunity to take part in an individual interview or a focus group together with other relatives.** Ensuring we sample all our data sources across different levels of the organisations, and across the full data collection time period in each Trust, we are confident this data sample should provide the breadth and depth of data we need to test our hypotheses.

6.3 Setting/context

This study will take place in Early Intervention Services (EIS) in the NHS in England (or teams with an equivalent function). EIS teams represent a highly accessible and universal point of access to mental health services for people experiencing first episode psychosis through a range of different referral routes including NHS, voluntary sector and self-referral. They support service users and their relatives. EIS teams were set up in response to good evidence of a "critical period" during the first 3 years of illness during which intervention is thought to be particularly effective in preventing longer term disability. Most teams work with people aged 14- 35 who have developed symptoms of psychotic illness for the first time, for a period of up to 3 years following first contact (though exact criteria vary between services). EIS teams generally consist of a mix of psychiatrists, psychologists, care coordinators (social workers, community psychiatric nurses, occupational therapists) and support workers.

6.7 Data collection

Data collection will require a mixed methods approach. We acknowledge that all methods have limitations, but used together, they strengthen the validity of the findings (48). At each site, the following data will be collected to address each of the study objectives.

Quantitative measures will be used to assess the uptake and use of REACT by NHS EIS teams and relatives (objective 1), to investigate the impact of REACT on self-reported relatives outcomes at each site (objective 4), and to investigate the resources (and costs) needed for successful implementation of REACT (objective 3). Specifically, we will assess the number of REACT accounts created for relatives to access the REACT site, and the level of use of each module using web analytic statistics. We will collect basic demographic information about all relatives on the site to audit which users the intervention is actually reaching. In addition, we will ask care coordinators to provide non-identifiable summary data relating to the number of relatives on their caseload who were not offered the toolkit and the number of relatives who were offered the toolkit but declined, and brief reasons why relatives were not offered or declined the toolkit. **Relatives who were offered the toolkit but declined, or did not subsequently access REACT will be invited by EIS staff or NIHR CRN representatives to take part in an interview or focus group to discuss their experience of being offered REACT.** No identifiable patient data will be transferred to the research team for relatives who declined or were not offered the toolkit, **or who declined or did not respond to the invitation to take part in an interview or focus group.** Relatives who choose to visit the site will also be invited by email to take part in the collection of outcome data, **and will have the choice of completing questionnaires, taking part in an interview, or both.** Following online consent, they will complete questionnaires to assess levels of distress (General Health Questionnaire-28; wellbeing (Carer

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Wellbeing and Support Scale); quality of life (EQ5D-5L) ehealth literacy (eHEALS); about their caring role; and to provide feedback on the REACT site. The measures were shown to be acceptable and sensitive to change in the feasibility trial. They will be offered at baseline and again after 12 and 24 weeks to ensure we capture short and longer term impacts within the timeframe of the study. Those who do not wish to take part in the outcome measures can still receive the REACT intervention and contribute anonymously to the implementation data. Resources will be identified using proformas designed specifically for this study. We will generate a list of the likely resources involved as part of Phase 1, and design measures to record this at each site. The proformas will be flexible to accommodate any additional resources identified during the process of data collection. Our team has considerable experience of collecting this kind of data using adapted versions of the Client Service Receipt Inventory (CSRI) which employs a similar approach to recording service input and then calculating cost using unit prices (49). All data from relatives will be downloaded to a database held at the CTU. Data to identify the critical success factors, facilitators and barriers to implementation of REACT (objective 2), will be primarily qualitative and will consist of:

- A. Stakeholder Reference Groups. The SRGs were initially proposed to be purely for consultation purposes and to inform data collection within the trusts and feedback on findings. However, after the first wave of SRGs their important contribution to understanding key factors relevant to implementation was apparent and so the SRG meetings will be transcribed and thematically analysed for research purposes. All participants will be aware of this at the point of recruitment and ask to consent accordingly.
- B. Interviews with key stakeholders (commissioners, managers, frontline clinical staff, relatives, and service users). Semi-structured interviews will be conducted face to face (preferably) but over the phone if needed. Focus groups (with up to 10 other relatives) will be offered to relatives as an alternative to individual interviews. We anticipate conducting up to 6 focus groups (1 per Trust), with focus groups facilitated by at least 2 members of the research team. The topic guide will focus on identifying facilitators and barriers, and testing hypotheses re implementation. Interview and focus group schedules will be open enough to allow new ideas to emerge, but will also target specific issues hypothesised to be important. Based on past experience we anticipate conducting approximately 20 interviews at each Trust. All interviews and focus groups will be transcribed in full and coded using NVivo software to aid data management.
- C. Document analysis-. Documents are most likely to provide data related to the context in which REACT is being implemented, but are likely to also cast light on the facilitation process. Examples of relevant documents are likely to include Trust Annual Quality Account; Psychosis Pathway; EIS Commissioning Spec and Operational Policy; CQUIN reports, Carers Strategy, Trust website and service user information leaflets; Complaints and SUI investigations; Service user and carer feedback. Interpretation of the contextual data from individual Trusts will be helped by comparison to nationally available data where possible, including the Mental Health Minimum Data Set (MHMDS) and National Audit for Schizophrenia (NAS). This will allow relative comparison of caseloads, referral rates, and duration of untreated psychosis (DUP).
- D. Observation of naturally occurring meetings will be recorded using proformas developed for the study and designed to capture the relevant information to test our hypotheses in each context. Examples of relevant meetings are likely to include Trust Board meeting; Adult Mental Health Quality and Performance Meetings; CQUIN target strategy; EIS business and clinical meetings; Carer's Strategy meetings; PPI strategy meetings.

We will be careful to ensure that we sample all our data sources across different levels of the organisations, and across the full data collection time period in each Trust.

6.8 Data analysis

1. Data will be analysed in a series of stages to inform the final Implementation Plan.
 - a. Within each Trust, data will first be analysed within data set (SRG focus groups, meetings, documents or interviews / focus groups), and then synthesised across these data sources. The initial analysis will be done at a coding level by the researcher, with input from the research team to identify key themes and to develop the analysis framework.
 - b. Within each Trust these frameworks will be presented in a workshop setting to the SRG within the Trust who will input into a synthesis of data across the data sources, and to draw out the key recommendations from the data that can be used to inform the Implementation Plan. During this process we will explicitly seek potential alternative interpretations of the data to maximise the validity of our findings
 - c. In the final stage, data will be synthesised across Trusts. This will be done by inviting all members of the participating Trust SRGs to a central meeting at which the key themes across all the data sources at each of the Trusts will be presented. A similar process of discussion will focus around identifying the key recommendations for a national Implementation Plan which will highlight common implementation factors likely to be relevant to all Trusts, but also variability, and include recommendations of ways in which implementation of REACT can be adapted to suit the specific needs of the Trust.

Quantitative data will be analysed in order to present outcomes in a clinically meaningful way to individual Trusts. Relatives' outcomes will be compared statistically at the different time points using repeated measures analysis of variance with time as the independent variable.

Qualitative data analysis will be guided by the use of framework analysis (50). This pragmatic approach is particularly useful for applied research in which data is synthesised from different sources

The initial analysis will be within data sets (interviews / focus groups, documents, observations) and later synthesised across data sets. Our initial framework will be derived from both an initial process of familiarisation with the data, and informed by our programme theory,. We will use the framework flexibly, recognising that emergent data may inform further development of the framework

The exact nature of the final plan will depend on the data collected and the input of the SRGs, but will include:

1. a video rationale for the use of REACT including research and policy context;
2. a step-by-step guide to successful implementation of REACT;
3. a Fidelity Scale to enable Trusts to self-monitor fidelity to the Implementation Plan;
4. online REACT supporter training toolkit;
5. a summary of resources needed to implement REACT;
6. measures/evaluation tools to evaluate uptake and outcome for relatives
7. case examples describing the process of implementation across participating Trusts – where the focus is on identifying and overcoming key barriers.

7. Dissemination and projected outputs

The main outputs from this research are:

(1) a national Implementation Plan to include: a video rationale for the use of REACT including research and policy context; a guide to successful implementation of REACT; a Fidelity Scale to enable Trusts to self-monitor fidelity to the Implementation Plan; Online REACT supporter training toolkit; a summary of resources needed to implement REACT; measures/evaluation tools to evaluate uptake and outcome for relatives; case examples describing the process of implementation across participating Trusts – where the focus is on identifying and overcoming key barriers.

(2) A workshop to facilitate the uptake of REACT by none participating EIS teams;

(3) A dissemination event focussing on development of theory underlying implementation of supported self-management interventions within the NHS that can be used to inform service development in other clinical areas where supported self-management interventions are being used for people with long term health conditions and their carers.

All outputs will be widely disseminated to all relevant stakeholders including NHS Trusts, national EI network (IRIS), service users, relatives, clinical academics and the general public. A website already exists which was developed for the pilot study and is being successfully used to disseminate findings from the pilot. This website will provide updates and outputs from the study and links to all publications and presentations – www.reactclinic.co.uk.

Journal articles outlining the main findings will be written for open access in academic journals (such as Health Services & Delivery Research Journal, BMJ, BJP), leading implementation science and service development journals (such as Implementation Science, Health Services Research, Psychiatric Services, Journal of Medical Internet Research). Publications aimed at service users and carers will be targeted at appropriate web and print forums (such as Carers UK, Your Voice (Rethink), Pendulum (Bipolar UK)). All articles will be adapted to suit the relevant audience and input from the whole research team will ensure these are accessible, appealing and informative.

Findings from the relatives' interview and focus group data will be written up as a doctoral thesis by a doctorate in clinical psychology student, (Johanna Barraclough), supervised by the CI.

Findings will be presented at key national and international conferences in each of the stakeholder forums, for example to clinicians and academics at the RCPsych Congress, British Association of Behavioural and Cognitive Psychotherapy (BABCP), American Association for Behavioral and Cognitive Therapies (ABCT), International Early Psychosis Conference and Rethink Mental Illness conference. We will also target conferences specifically focussing on implementation issues such as Health Service Research (<http://www.health-services-research.com/conference/>) and Knowledge Mobilisation Forum.

To broaden dissemination as widely as possible, we will develop a social media strategy to promote our findings using twitter, facebook, and key mental health blogs (e.g. Mental Elf, Mental Health Today). We will build on links with carer networks to promote findings to local groups and work with national organisations such as MIND, Carers Trust, McPin Foundation, Rethink Mental Illness, and Carers UK to promote findings on their websites. Finally, we will work with the Science Media Centre and University press offices to engage with the news media where possible. Although the intervention is currently written specifically for relatives in the NHS in England, it could easily be adapted to meet the needs of relatives in other countries. Our links with the International Society for Psychological and Social Approaches to Psychosis (ISPS) and International Early Psychosis Association (IEPA) will facilitate international dissemination. Since publication of the REACT feasibility trial, we have had interest from clinical teams from Norway and New Zealand and we are collaborating on Implementation Plans to help them adapt REACT for use in their own services.

The IAPT programme (Increasing Access to Psychological Therapies) is currently expanding from depression and anxiety to include more severe and enduring mental health problems including psychosis. The lack of supported self-management interventions has already been highlighted as a significant issue, especially given the success such approaches have had in increasing access to therapy for people with depression and anxiety. It is not clear to what extent "low intensity" interventions are suitable for service users with more severe mental health problems, but our pilot data suggest that supporting relatives with supported self-management interventions is highly acceptable and feasible, but not currently available. Filling this gap by developing REACT must be followed by ensuring it is disseminated within these organisations that will determine wide clinical use. Our research team include members of both the NICE Guideline Development Group (Johnson) and the IAPT Expert Advisory (Jones) and Training Task Groups (Lobban, Jones). Our team (Rycroft-Malone) also includes the Chair of the NICE Implementation Strategy Group which will ensure findings are also contributing to the advice this group provides on implementing Clinical Guidelines. The main direct beneficiaries of this research will be relatives, who will receive the information and support they need and should be able to access, but currently are often unable to do so. As well as reducing distress and improving outcome for relatives, the intervention is likely to have a significant indirect impact on other family members including the service user. If relatives feel more able to cope, have more information and strategies to manage psychosis and are involved as partners in the care team, they are more likely to continue to care. There is good evidence that where relatives are involved, service users have a significantly improved outcome(6), and that working with families is a clinically and cost effective way to reducing frequency of relapse and hospital admissions, and improve social functioning for service users with psychosis (2, 34, 51). The other direct beneficiaries will be clinical staff, who by effectively engaging relatives as partners in care, make their own role more manageable. NHS Trusts will benefit from being able to meet their clinical targets to provide widely accessible support to relatives. Indirectly, the whole of society will benefit from the improved wellbeing of significant part of the population, and the costs saved by the improved mental health of service users and relatives. Given the potential generalisability of these findings to implementation of other self management interventions, and the potential for REACT to be

adapted for relatives of people with other kinds of mental health problems, the indirect beneficiaries of this research are extensive.

8. Plan of investigation and timetable

Phase	Time	Milestones		
		Management	Resources	
Pre-start	-4 – 0 months	Ethics, R&D, appoint key staff	Research team (unfunded)	
Phase 1 a. Theory development and specification of implementation hypotheses b. Offer REACT and Implementation Plan v1 to all Trusts	Months 1-6	Theory Development a. Scoping review b. Review of implementation data from the feasibility trial c. Stakeholder workshops in North and South d. Version 1 of Implementation Plan Development of IPv1 All Trusts given REACT and IPv1 Development of online system for data collection (NB adapted from REACT trial)	Research fellow x 2 – Stakeholder workshops at each site (1 North and 1 South)	
Phase 2 Case study data collection	Wave 1 7-24 months	2 x Trusts- ongoing data collection and analysis (stakeholder reference group held 6 monthly at each Trust)	2 x 2 stakeholder workshops	
	Wave 2 12-24 months	2 x Trusts- ongoing data collection and analysis (stakeholder reference group held 6 monthly at each Trust)	2 x 2 stakeholder workshops	
	Wave 3 18-24 months	2 x Trusts- ongoing data collection and analysis (stakeholder reference group held 6 monthly at each Trust)	2 x 2 stakeholder workshop	
	Ongoing implementation and relatives' outcome data collected at all Trusts		Online system for data collection (already set up for REACT trial)	
Phase 3 Finalise Implementation Plan and dissemination	Year 3 months 25-30	(a) Stakeholder workshop across participating Trusts	1 Stakeholder workshops across Trusts 1 Generalisability workshop 1 Seminar	

		(b) Workshop to facilitate generalisability to none participating Trusts; (c) Dissemination seminar for mental health service developers and implementation scientists, focussing on broader implications for supported self management interventions for long term mental health conditions. Final Implementation Plan Analysis of costing and resources		
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9. Project management

The overall responsibility for the delivery of the project to time and budget will be held by the CI (Lobban). Her role is supported by the project team consisting of the co-applicants. The entire project team will meet every 3 months throughout the period of the study to monitor progress and problem-solve issues that arise (combination of face to face and teleconference).

A site researcher will be employed at the North site (supervised by site leads Jones & Lobban) and the South site (supervised by site lead Johnson). They will be integrated into established clinical research teams, providing access to broader clinical and academic infrastructure and peer support. Site leads will provide supervision to site researchers as required, but a minimum of fortnightly face to face meetings.

A senior IMPART lead will be identified within each Trust who will lead the collaboration between the research team and the Trust. This will be someone within the Trust who can identify and provide access to key data sources required for the study. They will meet regularly (approximately fortnightly) with the site researcher to facilitate access to data. A Stakeholder Reference Group (SRG) will be set up at each of the participating Trusts. The role of this group is to ensure the perspective of all stakeholders is integrated into the research and to understand SRG members views about implementation of REACT to inform research outcomes. Groups will be set up during Phase 1. Configuration of the groups will be flexible, but will include the following stakeholders: Senior Trust Board members or service leads; team managers; support workers (x2); relatives(x2); service users(x2). Each group will be chaired by the PPI site lead (Minns in the North and Pinfold in the South) and co-facilitated by the Trust IMPART lead, and the researcher at each site. This group will meet at strategic points throughout the study and specifically at the outset and towards the end of each detailed case study. They will inform pre-implementation outcomes, implementation data synthesis and guide the process of iterative data collection to ensure hypotheses are generated and tested at each site.

Workshops and seminars to synthesise data across Trusts, and to explore generalizability to none-participating Trusts will be led by our EIS lead Professor Smith and facilitated by other members of the project team. Our Implementation Science seminar in which we will present the broader implications of the findings for other mental health services, and for the development of implementation theory, will be led by our implementation expert Prof Rycroft Malone. Methodological guidance on statistics and collection of REACT delivery cost data will be provided by Sutton and Hollingsworth (co-applicants).

In accordance with the HS&DR Research Governance Guidelines, A Study Steering Committee will provide overall supervision for a project on behalf of the Project Sponsor and Project Funder and to ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. Nominations are:

Chair: Professor David Kingdon, Professor of Mental Health Care Delivery at the University of Southampton, UK, and honorary consultant adult psychiatrist for Southern Health NHS Trust. He has previously worked as Medical Director

for Nottingham Health Care Trust and Senior Medical Officer (Severe Mental Illness) in the UK Department of Health. He now does policy and implementation work for NHS England and is editor of their mental health websites.

A Relative: to be recruited through the NIHR Clinical Research Network PPI database once funding is confirmed. This will ensure they are independent from members of the study team. I have contacted CRN who are happy to facilitate recruitment to this role and I have costed time for the post as directed by them at £150 per meeting (4 across the study), including all travel, preparation and tasks.

Senior Clinical Academic with relevant methodological expertise: Professor Gunn Grande, Professor of Palliative Care at the University of Manchester who brings expertise in health services research, and specifically real world exploration of how support is delivered to relatives, using a range of quantitative and qualitative approaches.

Senior NHS Manager in Early Intervention Services for Psychosis: Dr Erin Turner, Consultant Psychiatrist Early Intervention Service, Solihull, who is interested in the use of technology in clinical mental health services.

This study will be run in parallel with an NIHR HTA funded trial evaluating REACT offered to a broader range of relatives, outside the NHS, supported by Expert Relatives. A sub group of the applicants (Lobban, Jones, Minns, Johnson, Murray and Liverpool CTU) will work across both studies to ensure complementarity and management.

10. Approval by ethics committees

Before the study commences we will gain ethical approval through the National Research Ethics Service (NRES), and the Sponsor (Lancaster University) and ensure we have NHS R&D approval at every Trust. All staff will have appropriate contracts, research passports, letters of access and have completed all mandatory Trust training. All staff will be up to date with training in Good Clinical Practice (GCP), taking informed consent (including for people lacking capacity), information governance training / information security, and assessing risk.

The site leads will oversee all data collection, storage, and management and ensure that this is anonymous and secure and consistent with the Data Protection Act (1998). Access will be restricted to preserve confidentiality and blindness. Data collection occurs at two levels. Analysis of the process of implementation and contextual factors is largely based on observation and analysis of SRGS, meetings and documents and will be done with organisational consent, ensuring all staff are aware of the process, and reporting no individualised data. All staff in the Trust will be informed about the study, the rationale, and the process of data collection, and given the opportunity to ask questions prior to the start. Where the researchers are present in a meeting, they will be introduced at the start of the meeting with an explanation of their role. The researchers will have honorary contracts with the participating Trusts and will adhere to all confidentiality and data protection policies within the Trust. An audit of the number of REACT accounts generated, demographics of the users, and use of the website will be collected regardless of whether relatives consent to taking part in the IMPART study. Relatives' usage data will be collected to inform feasibility and acceptability outcomes including auditing the resources and costs to deliver REACT for each Trust, and understanding which population groups are being supported by this intervention.

The second level of data is individual interview / focus group and outcome data and this will require individual written informed consent for each participant.

We do not anticipate any significant risk to participants or staff. Data will primarily collected on NHS premises, but if any interviews are conducted off site, then lone worker policies of the research teams will be followed. Participant Information Sheets will direct people to independent sources of support for either emotional distress, or to raise any concerns about the research.

11. Patient and Public Involvement

This study has extensive PPI throughout all stages of the design and delivery. The original REACT feasibility trial had relatives involved within the research team as researchers, relatives were on the TSG and the project team included a co-applicant who is a relative of someone with a long history of schizophrenia who was also part of the research team in the feasibility trial for REACT (Minns: aka Chapman for the purposes of publication). The data collected within the trial provided a strong support that REACT was well received by carers. In this application we have the same relative as a co-applicant (Minns) and her role will be Public Involvement lead at the North site, matched by Pinfold (Director of the McPin Foundation to promote user involvement in research) at the South site. Pinfold was

also involved in the original feasibility trial and runs the McPin Foundation charity that promotes best practice PPI in mental health research. Their role will be to represent the views and needs of service users & relatives throughout the research process, by drawing on their contacts within service user and carer networks and to Chair all of the Stakeholder Reference Groups (SRG) in each of the participating Trusts. Minns and Pinfold will ensure the SRGs have active involvement of service user and relative experts from each Trust, and support them to contribute to decisions within the study over what data to collect, content of the Implementation Plan, synthesis of findings and study recommendations. Both will also ensure that findings from the study are effectively disseminated to service user & relatives audiences. They will support the Trusts to ensure appropriate involvement of service users & relatives in the Stakeholder Groups, and provide training, supervision and support to these stakeholders around the process of research to maximise their input. We have costed for the time of the co-applicants and the input from of service users and relatives within the SRGs, and for additional analysis and dissemination time. We anticipate that involving relatives will improve the delivery of the project, the experience of relatives in the research process, and how effectively the findings are disseminated. This study has extensive PPI throughout all stages of the design and delivery.

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