RECO NIHR128128: The RECO study: Realist Evaluation of service models and systems for CO- existing serious mental health and substance use conditions (V.2)

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Study Title	RECO NIHR128128: The RECO study: Realist Evaluation of service models and systems for CO- existing serious mental health and substance use conditions.
Internal ref. no. (or short title)	RECO study
Study Design	Realist Evaluation using Mixed Methods
Study Participants	The focus of the study is on those people who use (and those who provide) treatment services aimed at or include people who have serious mental illness (SMI) and co-occurring alcohol/drug use. Inclusion: people who experience an SMI such as schizophrenia, bipolar affective disorder, schizoaffective disorder, delusional disorder, severe and enduring depressive disorder. (*people with diagnoses of personality disorder will be included if this is in addition to having an SMI as listed above) AND co-occurring use of alcohol and/ or drugs* ** drugs could include alcohol, heroin, cocaine, cannabis, cannabinoid receptor agonists and other novel psychoactive drugs as well as non-medical use of medicines and solvents*
Setting	Care and treatment provision that explicitly (through a model of treatment, or organisation of care) addresses both mental health and substance use. This is expected to mainly occur in within statutory mental health provision and/or substance use services. However, other relevant services will also be considered such as homeless services. Third sector support services will also be of interest if they provide care for people with COSMHAD
Planned Study Period	1.1.2020 to 31.07.2022

Research Questions	1. What does the existing literature suggest 'works' (demonstrated by engagement and other health outcomes) in terms of COSMHAD, for whom, and in which circumstances? 2. What are the current range and types of service systems that currently operate in the UK that aim to improve engagement and health outcomes for people with COSMHAD 3. What are the specific resources, contexts, and mechanisms that make COSMHAD models successful or not, for whom and in what contexts.
Research Objectives	1. To undertake a Realist review which aims to examine evidence from a realist perspective in order to identify the contexts mechanisms and outcomes for the development of a programme theory as well as inform the subsequent work packages. 2. To identify services and treatment programmes that specifically address the multiple needs of people with COSMAD. This will be undertaking by an initial mapping and then a more detailed survey of the models of care, remit and model of care provided and to whom. 3. To undertake focus groups and individual interviews in 6 case study sites with service users, carers and providers in order to further refine the programme theory and identify areas of priority for further research.

Abbreviations

CCG Clinical Commissioning Group
CMO Context, Mechanism outcome
COSMHAD Co-occurring serious mental illness and alcohol/drug issues
IAPT Increasing Access to Psychological Therapies
NHS National Health Service
NICE National Institute for Health and Care Excellence
SMI serious mental illness

BACKGROUND AND RATIONALE

Approximately 30%-50% of people with serious mental health problems (SMI) have a co-existing alcohol/drug condition [1, 2]. For the purposes of this study, serious mental health is defined as those conditions that every affect daily functioning and quality of life, as well as requiring long term support from services [3]. This includes psychotic disorders such as schizophrenia, paranoid psychosis; schizoaffective disorders; bipolar affective disorders; and long term and severe depression. In alcohol and drug treatment services, 70-80% of serve users have co-morbid mental health problems [2] and these tend to be depression, anxiety and personality disorders with SMI less prevalent. Co-Occurring Serious Mental Health problems and Alcohol/Drug use (COSMHAD) is associated with a significant impact on health and social outcomes such as Increased risk of suicide and self-harm [4]) and violence perpetration and victimisation [5, 6]; contact with the criminal justice system and forensic mental health [7], mental health and substance use treatment recidivism and crisis care [8]; Higher overall service costs than those with single diagnoses [9]; co-morbid physical health problems [10], and social problems such as homelessness [7].

There is limited evidence to inform treatment. The evidence to date comprises of evaluations of psychosocial interventions [11]; Integrated Treatment models [12], and evaluations of training the workforce [13]. None of these approaches has so far provided a definitive answer as to how services and treatments should be best delivered to improve health and other outcomes for this group. One of the challenges of undertaking research with people with COSMHAD is that it is a very heterogeneous group, not only in terms of type of mental health problem, but also in terms of the type and severity of alcohol and/or drug use. Research studies often exclude those who are currently mentally unwell and/or those who are unable to commit to participation in a study for many reasons such as childcare, homelessness and other barriers. Therefore these studies only provide results for a sub-section of the population who experience COSMHAD.

In the UK, a policy of “mainstreaming” has been advocated in response to the high levels of co-occurring mental health and substance use across mental health, drug and alcohol and other support services (such as housing, social care, criminal justice sector) [14]. Mainstreaming advocates that the workforce in the relevant services should have the appropriate training and capabilities to be able to offer treatment that addresses both mental health and substance use. This also requires clinical leadership to offer training and support to implement this at a local level. Key agencies should work together to develop agreed care pathways to ensure that people with co-occurring mental health and alcohol/drug issues get the right help in the right place at the right time. This work is supported by NICE guidance which was informed by a review of evidence as well as expert opinion [15]

In 2018, a refreshed policy guidance [16] has been published which broadly reflects the original principles of mainstreaming i.e. its “everyone’s job” and there should be “no wrong door” for people trying to access help, but it also broadened its remit to consider the wider health and social care sector including the third sector providers of substance use treatment, and the growth of volunteers and peer support. However, there is still significant uncertainty about how care should be delivered, under what contexts it works (or doesn’t work) and whether there needs to be a range of approaches that meet the needs of such a diverse group.

Therefore, the aim of this funded project is to use a Realist approach [17] understand what works for whom and in what context by synthesising data from published and grey literature, mapping and describing the characteristics of UK services and service provision, and undertaking in depth focus groups and interviews in locations picked to be representative of the range of provision identified in the mapping and review of literature. The outcome will be a refined programme theory that can be used to inform future research, policy and practice.

OVERALL DESIGN AND THEORETICAL BACKGROUND

As already set out, services for people with co-existing serious mental health and alcohol/drug conditions are complex systems with outcomes that could be affected by numerous compounding factors such as the type and severity of the mental health or alcohol/drug condition, the interplay between the two, their age, gender and ethnicity, as well as previous experiences of seeking help. Realist approaches are theory driven approaches used to understand complex interventions; they account for context and mechanisms as well as outcomes in the process of systematically and transparently synthesising relevant literature or analysing relevant data [18]. Applying realist approaches offers the potential to describe why interventions or services for COSMHAD, are successful or unsuccessful, in complex social systems [19] through focusing on 'what works, for who, in which circumstances'.

Realist approaches attend to the ways that interventions (or programmes) may have different effects for different people, depending on the contexts into which they are introduced. An intervention or service for people with COSMHAD, is considered to provide resources that alters the context into which it is introduced triggering a change in the reasoning of intervention participants, leading to a particular outcome i.e. Context + Mechanism = Outcomes (or CMOs) are used as explanatory formulae (otherwise referred to as realist programme theories), which are then 'tested' either through literature (synthesis) or empirical data (evaluation) and refined as the project progresses. They, in effect, postulate potential causal pathways between interventions and impacts. Thus, use of a realist approach will help to expose the multiple resources delivered as part of services for COSMHAD the ways that these may be employed with different people, and how these generate different outcomes. Furthermore, with any service or intervention, implementation can lead to the programme being interpreted and/or utilised differently, with possible impact on outcome [20]. Realist methodologies aid the development of a broader picture of how such combinations of context and underlying causal mechanisms can improve or impair programme fidelity and efficacy.

Realist synthesis (WP1) methods will provide valuable insights into literature ideals and develop and refine an overarching programme theory of what works, for who and in which circumstances. System mapping (WP2) will then allow for broader understanding of UK provision.

A realist sampling strategy is determined through the programme theories to be investigated. These programme theories frame the choices made about who or what to sample in the research [21] Interviewees are chosen based on their 'CMO investigation potential' as each component in the CMO configuration requires different respondents. For example, practitioners will often have seen many successes and failures in COSMHAD services and therefore will have information on when and with whom they are most successful, and also importantly when and why it is not.

Data collection and analysis is detailed in each specific section below; overall analysis will employ a realist logic to make sense of, test and refine the programme theories throughout all three phases (synthesis; service mapping; focus groups and interviews). Qualitative data will be transcribed verbatim and imported into NVivo alongside literature from the synthesis and analysed using a realist CMO lens; all primary and secondary data will be analysed in NVivo. During the evidence synthesis and data collection, we will move iteratively between analysis of particular examples, refinement of programme theory, and further iterative searching for data to test [22]. Data from all sources (literature and primary data) will be integrated. Within the context of the realist review, we will also attempt to identify the resource (monetary and non-monetary) (consumed and saved) and health outcome implications (costs and consequences) attached to the programme theory CMO configurations identified through the realist review in WP1. The resource and outcome implications will be refined throughout WP2 and WP3. In addition, where possible, we will collect primary resource use and outcome data.

Service provider data will be collected through the audit conducted in WP2. We have included detailed questions in the audit designed to collect direct and indirect resource use and outcome data (examples may include: equipment and materials, staff training and time, patient stays etc). Patient data on resource use and outcome will be identified from the focus groups conducted in WP3. These will be supplemented with data from the literature and documentary evidence provided to us from the services included in the audit and focus groups, and refined in the focus groups in WP3.

Given the multifaceted approach, the research is described in three distinct phases in the in order to maintain clarity. However, the overall research process is much more iterative, cycling between literature searching and data collection, and constant refinement of, adjudication between, and evidencing of emerging programme theories.

STUDY PROCEDURE

Workpackage 1 involves a Realist Synthesis of published and grey literature in order to generate initial programme theories which will be tested out in the audit of identfied COSMHAD services in the mapping in Work package 2 and the focus groups in work package 3.

WORKPACKAGE 2 MAPPING OF NATIONAL SERVICE SYSTEMS (MONTHS 1-24)

WP2 Service Mapping

The RECO study is based on realist methods. Realist approaches attend to the ways that interventions (or programmes) may have different effects for different people, depending on the contexts into which they are introduced. This is commonly parsed in terms of a realist programme theory, where Context + Mechanism = Outcomes. By conducting the mapping exercise we aim to uncover the variety of different contexts in which COSMHAD treatment operates.

Stage 1: The initial stage of the mapping exercise entails contacting all potential providers of COSMHAD services across the UK in order to gain a broad image of service provision. This primarily constitutes freedom of information requests sent to Local Authorities and NHS Mental Health Trusts, as well as third sector care providers, asking for basic information about commissioning of specific COSMHAD treatment pathways and local approach to the treatment of those with COSMHAD.

Stage 2: The second stage of the mapping aims to develop a more detailed picture of a smaller subset of these treatment providers. Treatment providers identified in the initial stages of the mapping will be sent requests to complete the audit online survey for more detailed service level information, conforming to the HRA definition of service evaluation/audit. We will also offer the alternative option of a phone call to collect this data. It is hoped that one individual from each provider (key informant) will be able to provide all of the necessary information. However, where treatment provision is split across multiple providers in the same area, it may be necessary to contact multiple people to collect all the necessary information.

WORK-PACKAGE 3: CONSULTATION WITH PROVIDERS AND SERVICE USERS AND CARERS (MONTHS 24-30)

WP3a Focus Groups and Interviews

We will undertake more in-depth Realist evaluation at 6 case study sites across the UK. They will be chosen based on representing a range of types of provision, and also a range of

geographical locations across the UK. We will aim to raise awareness of the study using organisational communications (such as weekly news briefings), circulating the poster PDF through email networks and through social media such as Twitter.

Recruitment and Consent
Potential participants will be approached by key contacts at each service (likely to be those in COSMHAD clinical leads) and consent to contact will be obtained and passed to the RECO team. The potential participants will be emailed an information sheet and a link to the online consent form and the relevant PIS. Once consent has been confirmed and logged on a password protected recruitment spreadsheet, the participants will then receive the details of the time and date of the focus group or interview and the method and instructions for joining remotely or in person. In the case of online focus groups or interviews service users and carers we will check that they have appropriate IT access and in some cases where there are financial constraints, we can offer a 4G data voucher to assist with joining the group on their device. In the case of in person focus groups and interviews, staff within the services will assist us in identifying a designated private room on the premises where the group can take place.

Data Collection
Focus groups and interviews (either in person on service premises or online using Microsoft Teams) will concentrate on 6 Case Study localities drawn from the services identified in WP2. The team have experience of successfully running similar focus groups remotely during the COVID pandemic (MIMOS Study Hughes Chief Investigator IRAS ref **238240).** Each case study will comprise of 5 small focus groups with approximately 6 people taking part in each virtual focus-group or one-to-one interviews with up to 12 service users and 6 carers. The focus group will be facilitated by at least two RECO researchers, experienced in conducting qualitative research and focus groups, and will last for approximately one hour (as suggested by our PPI group). Participants will take part in a single session. We originally planned on having mixed care provider and service user focus groups, but on consulting our PPI group about this they suggested against it, citing concerns over the ability of service users to feel able to respond openly and honestly about their experiences of receiving services in the company of providers. We will remind all participants to respect the confidentiality of the focus group discussions. Interviews will be facilitated by one RECO researcher experienced in qualitative research and last for approximately one hour. If someone becomes distressed, we have the option of meeting them in a virtual break-out room or designated private room on the service premises where one of the facilitators will be able to have a private conversation. All service user and carer participants will be offered an optional de-brief call after the focus group or interview. We will inform the participants in the online focus groups that their name will be visible during the focus group but all data will be anomymised for analysis. The researcher will adhere to the Liverpool John Moores University lone researcher policy when undertaking individual interviews on service premises.

WP3b Individual Interviews with Service Users
We also plan to undertake interviews with a purposive sample of people with COSMHAD to include the voices of those who may find the focus groups too challenging to engage with. This will be submitted as an amendment to this IRAS application, as we will be informed by the work we have described in this application and further PPI engagement as to the sampling framework and the topic guide itself.

DATA MANAGEMENT AND ANALYSIS

All data will be analysed using a realist logic of analysis [18] to make sense of, and to test and refine the programme theories. NVivo will be used to manage the majority of data collected, which will be analysed using a realist Context Mechanism Outcome lens. Data from all sources will be integrated meaning that interview data will be understood in light of the realist review

and stakeholder focus groups. The analysis process will involve moving iteratively between analysis of particular examples, refinement of programme theory, and further iterative searching for data to test. The data will be synthesised in order to fill in gaps in the knowledge and further refine the programme theories. A realist logic of analysis will be utilised and data from all sources will be integrated.

WP2
The mapping exercise is not intended to produce any data to be analysed, rather a description of services across the UK. Data form the service audit survey will be used descriptively and analysis of any quantitative data from the service audits will be supported by the statistical software package IBM SPSS (IBM, Armonk, New York, USA). Data will be summarised using appropriate summary statistics (eg, mean, median, proportion), depending on the level and nature of the data (eg, parametric, non-parametric, ordinal, frequency). Likewise, inferential analysis (eg, t-tests, Mann-Whiney U tests, $\chi 2$ tests) will be used as appropriate to the data to complement, inform and support qualitative analysis

WP3
Interviews will be digitally recorded (with participant consent) on an encrypted recorder (in line with General Data Protection Rights) and transcribed verbatim. Facilitators will also take field notes and collate written materials produced by the participants. These notes will then be collated by the research fellow who facilitated the event into one secure online document for analysis. Throughout the data collection period the research team will partake in an iterative data analysis approach. This approach is a deeply reflexive process, whereby it is key to spark insight and develop meaning. It consists of multiple rounds, revisiting the data as new additional questions emerge and connections are established, thus deepening the understanding and meaning of the findings [30]. This continuous loop of analysis allows the research team to connect emerging insights, themes, and concepts, by continually constructing and reconstructing their understanding of the programme being investigated.

OUTPUT: a refined Programme Theory which can inform recommendations for service development for specific groups and contexts, for commissioning, and future evaluative research.

MEASUREMENT OF COSTS AND OUTCOMES
Whilst there is not the scope or remit within this study to undertake an economic evaluation of the services, we will attempt to identify the resources (monetary and non-monetary, consumed and saved) and health outcomes attached to the programme theory CMO configurations identified in WP1. Resource use and outcome data (from an NHS perspective) will be identified from the literature and through the audit conducted in WP2. A detailed pro-forma will be designed for the audit to collect direct and indirect resource use data (examples may include: equipment and materials, staff training and time, appointments with healthcare etc.). Resource use and outcome data from a patient perspective will be identified from the interviews conducted in WP3. Values for both resources and outcomes will be derived from primary and secondary sources. These will be used within WP3 to assist in refining the programme theories. Recommendations for future health economic research will also be articulated within WP3.

DISSEMINATION AND IMPACT
Dissemination We have several routes into dissemination of study findings. The main one will be using our links with several bodies including (but not restricted to) the Devolved Nations health and social care policy makers, Public Health England and NHS England (national and regional), the NHS Mental Health Nurse Directors, PROGRESS (http://www.dualdiagnosis.co.uk), British Psychological Society Faculty of Addiction (https://www.bps.org.uk/member-microsites/dcp-faculty-addictions); Substance Misuse NHS

providers alliance (SMPA) https://www.nhs-substance-misuse-provider-alliance.org.uk) , and the third sector providers group (Collective Voice https://www.collectivevoice.org.uk/about-us/). We will use social media (SoMe) from the start of the study to raise awareness and gather followers. We will also have a study webpage at the University of Leeds on which we can post information about who we are and what we aim to do, as well as post lay summaries and links to publications that arise from the work packages. Our intention is to disseminate findings as they emerge rather than at the end of the funded study. One way of doing this is to generate accessible summary reports to correspond with each steering group meeting (4 times a year) which will be available on our website and promoted via our professional and lay networks as well as via social media. In addition to social media we will use a series of blogs to discuss the progress and emerging findings. We will be able to generate a set of research priorities which will be identified by consensus at the final dissemination event. We will produce a report at the end of the study to the NIHR. In addition, we anticipate at least 3 gold open access main journal papers based on each of the work packages and use the research programme as a case study to describe the use of realist methodology in understanding health services. We will be able to generate a set of research priorities which will be identified by consensus at the final dissemination event. We will produce a report at the end of the study to the NIHR.
Outputs: The main outputs will be the realist synthesis of the literature, the mapping and service descriptions, and the Programme Theory that is refined by stakeholders in work package 3. Using these three outputs

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