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

Version Control

Version 1	**12th February 2020**
Version 2	**12th March 2020**

2: 12th March 2020

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Committees	Project Management Group (PMG) Independent Oversight Group Program Steering Committee (PSC) Lived Experience Advisory Group (LEAG)

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; and criminal justice services (prison healthcare; healthcare services in courts and police cells). Third sector support services will also be of interest if they provide care for people with COSMHAD
Planned Study Period	1.1.2020 to 31.12.2021

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 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.

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

WORK PACKAGE 1: EVIDENCE SYNTHESIS

We will explore the literature based on two approaches: (i) to purposively identify, map and describe the literature on the types of provision; and (ii) using a realist logic of analysis that develops, tests and refines programme theories.

Search strategy

We will construct a comprehensive and inclusive sampling frame to guide mapping. This will aim to capture diverse literature on types of COSMHAD service provision. These searches will also inform the early phases of the realist synthesis and the explanatory searching of the literature that will follow. We will identify both conceptual papers and empirical research studies through systematic searches of the following bibliographic databases: Cochrane Central Register of Controlled Trials; MEDLINE (Ovid); Embase (Ovid); CINAHL (EBSCOhost); PsycINFO (EBSCOhost); Web of Science; and HMIC (Ovid).

Our search strategy will draw on strategies used in previous systematic reviews such as the Cochrane Review of psychosocial interventions for COSMHAD [11]. We will undertake extensive searches of selected grey literature sources: including bibliographic databases (e.g. OpenGrey), web-based search engines, practice-orientated magazines (e.g. Drink and Drugs News), UK Higher Education repositories, and organisational websites. Supporting evidence used in the development of NICE Guideline NG58 [15] and recent PHE guidance [16] on COSMHAD will also be searched.

Review strategy

(i) Mapping review of types of provision for people with COSMHAD

We will map the literature to provide a systematic overview of the published literature on the types of COSMHAD service provision. We will select studies of any type of intervention, service or model in high-income countries. One reviewer will screen all articles and two reviewers will independently second screen a random subset (20%). We will prioritise evidence generated within a UK (or related High Income Country) context to purposively build up clusters of related papers of types of COSMHAD services provision. A data extraction form will be developed, piloted and refined to capture detailed information about intervention components and sub-components. One reviewer will extract data from the included articles and a random selection of 10% checked for quality by a second reviewer. The development of a detailed typology of COSMHAD service provision will be informed by relevant treatment models; e.g. Drake's Integrated Treatment Model [12] . The results will be used in WP2 to systematically identify and categorise the range and types of service systems that currently operate in the UK.

(ii) Realist synthesis

Realist synthesis is a theory driven method for the systematic review of complex interventions; it identifies generative mechanisms in context to understand outcomes in the process of systematically and transparently synthesising relevant literature [22]. We will follow the 5 steps of realist synthesis mapped out by Pawson (2006) [23] and conform to the RAMESES I quality standards [24]. Although presented linearly, the synthesis process will be iterative and in constant triangulation with primary data collected in WP3.

Focusing the synthesis: The overall focus of the study is to develop realist programme theories for COSMHAD service provision. The mapping searches will be used to further focus the synthesis and refine aspects of the review questions at this early stage. We will draw on stakeholder knowledge through WP3.

Developing initial programme theories: We will explore, refine and prioritise the candidate programme theories relevant to the review question(s). This will draw on further iterative consultation with our stakeholder groups through WP3, and include both explorative and formal searches of the literature to locate current theories. The aim is to develop a set of programme theories using, wherever possible, explanatory 'If… then' statements which specify context, mechanism and outcome.
Developing a search strategy: Informed by the findings of the mapping review, we will follow the Booth et al guidance [25] to develop a search strategy. The search will be driven by the objectives and focus of the realist synthesis and use the CLUSTER searching technique [26] to harvest documents from diverse sources for theory development, refinement and testing. An iterative approach to searching will be undertaken as our understanding of the topic area increases.
Selection & appraisal: We will include articles based on their potential contribution to theory building and testing [23]. Screening at all stages will be conducted by one reviewer with quality assurance through independent screening of a random subset of documents by two reviewers. Additional discussion and/or joint reading will occur to resolve uncertainties and/or disagreement between reviewers.

Data analysis & synthesis: The selected literature will be analysed in NVivo using a realist Context Mechanism and Outcome (CMO) Configuration lens [18]. Throughout the synthesis, we will move iteratively between analysis of particular examples, refinement of programme theory, use of abstract (or middle range) theory and further iterative searching (e.g. using tailored methods such as BeHEMoTh [27]. For each engagement or other health outcome (O) identified, we will seek an understanding of the mechanism (M) and under what contexts (C) the mechanism has been 'fired'. Underpinning common mechanisms between studies will then be sought and tested. We will also attempt to identify and examine the resources (both monetary and non-monetary) (consumed and saved) attached to the programme theory CMO configurations. The analytical process will involve note taking, highlighting and the giving of approximate labels, and we will use data extraction forms to assist with the organisation and collation of data. This process of analysis and synthesis will be iterative and complex in line with a realist approach. We will present the final synthesis as a narrative, and draw upon figures and summary tables where appropriate.

WORKPACKAGE 2 MAPPING OF NATIONAL SERVICE SYSTEMS (MONTHS 1-12)

An initial search for services specifically targeting COSMHAD will be commenced as soon as the study starts. We will use a snowballing method via our contacts and networks (such as PROGRESS, NHS SMPA, Public Health England, NHS England/CCG, social media, NHS mental health Nurse Director's forum) to identify the range of services that provide dedicated services, models, interventions or care pathways for COSMHAD.

At this stage, our definition of what is included as a service or provision will be sufficiently broad to be inclusive, but must meet the aims of the study in that:

- It is a service that explicitly contains elements of provision for people who meet our inclusion criteria
- Has a written service level agreement or guidance which describes what is offered and to whom In relation to COSMHAD.

OUTPUT: List and basic description within a spreadsheet

2nd stage

An audit template will be developed by the RECO team and advisors and will be informed by the emerging findings of the realist review (WP1) to map and capture details of provision across the United Kingdom (England, Scotland, Wales and Northern Ireland). As each service is identified, they will be sent an online survey (audit template) that will be supplemented with brief telephone interviews with key informants (such as a lead COSMHAD clinician). We will also request any service specifications and protocols. In order to optimize response rates, we will utilize our local contacts and connections to encourage responses. We will contact people by phone and email to arrange a convenient time to complete the tool if this is required. If needed, we can use Freedom of Information requests to gain some information. The content is likely to capture the following:

• The type of provision- e.g. mainstreaming, parallel, integrated, link worker/champion model, specialist lead clinician, workforce development (training and supervision) trauma informed provision and psychologically informed environments, stand-alone posts (e.g. Consultant nurse

• Who or what provision is commissioned to deliver (based in MH, based in sub use, NHS, social care, third sector, housing, and criminal justice system)

• The nature of the care pathway and/or joint working agreements, and whether this is formally agreed or informal

• The number and type of whole time equivalent staff (WTE) and grades (specifically to deliver the provision).

• Remit of the provision inclusion criteria, type of input offered etc. screening, assessment- types of assessment, psychosocial interventions – are they trained and supervised for this? Evidence based?

• What types of people access and engage with the services.

• If relevant, what type range of treatment offered - e.g. brief advice, assessment, detoxification, psychosocial interventions, psychological therapies, social and educational (recovery), harm reduction, recovery etc.[21] and timeline of provision.

We will create a matrix of types and components of services in order to generate a typology of services across England and the Devolved nations. This will inform our sampling strategy for Work Package 3.

OUTPUT: A summary of the service mapping and service audit will be shared with relevant health and social care commissioners, Department of Health in England and the Devolved countries.

WORK-PACKAGE 3: CONSULTATION WITH PROVIDERS AND SERVICE USERS AND CARERS (MONTHS 9-18)

This WP comprises two components: stakeholder focus groups (WP3a), and individual interviews (WP3b) with a purposive sample of people currently experiencing co-existing severe mental health and alcohol/drug conditions. This will take place at 6 sites across the UK.

We will request relevant service- related documents and undertake a documentary analysis in each of the chosen sites. This may include any audit or evaluation reports that have been conducted in the last 5 years, especially if these include information on health outcomes and/or retention rates in treatment. There may also be some serious incident reviews such as Domestic homicides and suicide enquiries that can often involve people who experience COSMHAD. This documentary analysis will be undertaken prior to data collection as it will inform the topic guide content for the focus group and interviews.

WP3a Stakeholder Consultation

Sampling: A sampling framework devised from the outcome of the mapping in WP2 and informed by the programme theories [21] will be employed to recruit a range of service users, carers, healthcare staff, prison care, CJS managers and commissioners comprising of 30 people in each locality (15 people who use or have used the local services, 15 practitioners and commissioners) and they will be invited to a stakeholder event.

Target population: People who use, commission or provide services in a defined locality specifically for those with serious mental illness and co-existing drug and/or alcohol use; all ages, NHS providers and third sector, charity and private providers, criminal justice, homelessness and social care services. We will not extend invitations to the stakeholder events for those services that only target those with common mental health issues (such as IAPT) unless they also provide a service for people with serious mental illness. We will exclude people and services related to organic brain disorders such as dementia. We will not exclude people with learning disability as long as they have capacity and also live with a serious mental illness and co-existing alcohol/drug use.

Data collection: Theory driven focus groups will be planned in each area (outlined above). The RECO researchers will work with local clinical contacts (with support from the co-applicants -GG, LM, AC, EG, EH, HS) to engage a wide range of stakeholders and service users; organise the invites and book venue and refreshments. The focus groups will be organised and marketed well in advance to gain optimal attendance; a convenient venue will be used and refreshments will be provided. The RECO researchers on the project will travel to the location to run the event with co-facilitators from the investigator team. This is to ensure consistency of approach and allow for an iterative process across localities. As each event is completed, the team will have a teleconference de-briefing to consider what data relevant to the programme theory is emerging, and refine the programme theories, and therefore also edit the questions asked at the next event. The focus groups will be audio recorded and transcribed verbatim.

WP3b Individual Service user interviews:

We will undertake individual realist interviews in two sites with a total of 10-15 COSMHAD service users. As previously stated in the research plan, the justification of this is to enable data to be collected from people with lived experience who are not likely to be able to attend the stakeholder events and are representative of people where care pathways may not work well, or they may be excluded from the identified services or treatments.

Pawson and Tilley [17] suggest a strategy for conducting qualitative interviews within realist evaluation studies, where theories are placed before the interviewee, in a conversational format, for them to comment on with a view to providing refinement. The subject matter of the interview is the researcher's theory, which will have been elicited in the realist review (WP1) and stakeholder focus groups. This relationship between the interviewee and interview – described as a teacher–learner cycle – is integral to realist evaluations. Three different phases can be outlined in realist interviews: theory gleaning, theory refining and theory consolidation [28]. The interviews will contribute to theory refining and consolidation phases. These interviews will be used to further develop and refine aspects of the programme theory that remain unclear based on the analyses of data from the realist synthesis; this approach has previously been successful [29] . Alternatively, they may

identify relevant data about aspects of the programme theory that have not been found in the literature. Additionally, there will be a focus on understanding when and why COSHMAD has not been successful and attempts will be made to understand the associated contexts and mechanism.
Recruitment: Working with our Public and Patient Involvement (PPI) group we will develop recruitment strategies and materials to ensure that we recruit people who are often less likely to get their voices heard (such as people who are homeless, women, people from black and ethnic minorities, and those in the criminal justice system).
A purposive sampling framework will be devised and used to ensure the representation of the range of service users are involved in the interviews. We will work with local care providers and peer workers to help identify people who are eligible to take part. We will advertise the study in community mental health settings, hostels, substance use services, probation, voluntary sector services etc. using a poster and leaflets. We will also use social media to raise awareness of the study. This will be done well in advance of the recruitment commencing. Potentiality eligible people will be able to contact one of the RECO researchers by phone, email or by social media to express interest.
Data Collection We will offer flexible appointments and locations, and offer travel reimbursements and £10 cash gift as an expression of appreciation for their contribution. Locations for interview will be flexible for the participant and can be face to face, phone or online (such as synchronous email interview). Working with our PPI group we will develop recruitment strategies and materials to ensure that we recruit people who are often less likely to get their voices heard (such as people who are homeless, those in the criminal justice system etc.). Informed consent will be obtained prior to interview.

Data management and analysis (WP3a&b). Interviews and stakeholder events 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 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 is 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.

Data will be analysed using a realist logic of analysis [18] to make sense of, and test and refine the programme theories. NVivo will be used to manage the data, then 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.
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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