Study Protocol

**The eCliPSE Project: implementing evidence-based eHealth interventions for comorbid mental health and alcohol/other drug use problems into health and community settings**

A 3-level cluster randomised controlled trial

with parallel complementary qualitative and survey methods for marketing research

FUNDING

This study is funded by the National Health & Medical Research Council Partnership Projects Scheme, G1801005

STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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## Glossary of Abbreviations

|  |  |
| --- | --- |
| **Abbreviation** | **Term** |
| eCliPSE | electronic Clinical Pathways to Service Excellence |
| MH | Mental health |
| AOD | Alcohol and other drugs |
| DtC | Direct-to-consumer |
| ITM | Integrated Translation Model |
| LHD | Local Health District |
| DDCAT/DDCMHT | Dual Diagnosis Capability in Addiction Treatment/ Dual Diagnosis Capability in Mental Health Treatment Audit Tool |
| ToFU | Top of the funnel |
| MoFU | Middle of the funnel |
| BoFU | Bottom of the funnel |
| CRM | Customer relationship management |
| CTR | Click through rates |

## Terms Used for Parties Involved in Study

|  |  |
| --- | --- |
| **Terms Used** | **Definition** |
| Service user, client, patient, consumers | These terms may relate to individuals who are engaged or enrolled in a mental health and/or substance use service |
| Registered user, user | These terms may relate to individual who register as a user of the eCliPSE online portal; see section 3.11 |
| Service, organisation | These terms may relate to mental health and/or substance use services or organisation recruited for the purpose of this study |
| Clinician, practitioner, service provider | These terms may relate to mental health and/or substance use professionals who work as clinicians, practitioners, or service providers at the recruited services within this study |
| Service manager | This term relates to the service manager or leader of the mental health and/or substance use services or organisations recruited for the purpose of this study |

# 1 INVESTIGATORS

## 1.1 Study Location

The Centre for Brain and Mental Health Research

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## 1.3 Partnerships

This project leverages long-term collaborations in comorbidities between the University of Newcastle, University of New South Wales, and University of Sydney. Additionally, this project has sought support funding from partner investigator *Beyond Blue.*

## 1.4 Funding and Resources

This study is funded by a grant from the National Health & Medical Research Council Partnership Projects Scheme, G1801005 and through partnership funding from partner investigator *Beyond Blue*.

# 2 INTRODUCTION

## 2.1 Background and Rationale

eHealth programs have been successfully developed for a range of mental health (MH) and alcohol/other drug (AOD) problems in attempts to address these issues (e.g. 9 systematic reviews in depression, 1). Over the last 10 years, the CI team has built an internationally recognised evidence base in MHAOD comorbidity prevention, early intervention, and treatment via the NHMRC Centre for Research Excellence in Mental Health and Substance Use (CIs Teesson, Kay-Lambkin, Baillie, Christensen). We are the first in the world to integrate eHealth into treatment provision for comorbid depression and AOD use problems (2, 3, 4, 5), binge drinking and depression (6-8), depression/psychosis and lifestyle problems (tobacco, poor sleep, poor diet quality, physical inactivity, (9), and crystal methamphetamine use and lifestyle problems (10). Each of these programs has been evaluated in at least one randomised controlled trial and has demonstrated efficacy as a stand-alone treatment.

Despite good evidence for program effectiveness, eHealth services in Australia exist largely independently of traditional healthcare service settings, with **mental healthcare providers underutilising eHealth systems** in their practice (11). This is **in contrast** **to** almost every other sector in Australia, especially the **commercial/corporate industries** (12). Thus, for all the advantages that eHealth treatments offer, and the substantive evidence base for their efficacy, their potential impact is unrealised. Stakeholders across sectors, levels of government, and the community, endorse the widespread adoption of eHealth into clinical practice. However, there are currently no systematic procedures or policies in place to facilitate the integration of eHealth programs into clinical practice in MH, AOD or any broader healthcare setting in Australia. To address this issue, our team has established a partnership between researchers at the University of Newcastle, the University of New South Wales, the University of Sydney, and the NSW Ministry of Health (CIs Kay-Lambkin/Teesson/Haber/Morley/Baillie). Over the past 18 months, our team has built the eCliPSE portal (google “eclipse portal”) that provides:

* Tailored information to ‘consumers’ (people experiencing MHAOD comorbidity) regarding MH, AOD, and related issues.
* 24/7 access to validated MH and AOD screening tools, and online treatment programs that are (a) evidence-based (at least one RCT of efficacy); (b) developed for the Australian context; (c) suitable for delivery with limited therapist contact; and (d) addresses comorbidity. A search of the literature identified the following 4 programs that met these criteria and are featured on the eCliPSE portal; depression & AOD use (2), binge drinking & depression in young people (13) healthy lifestyle in people with depression (9), and crystal methamphetamine and lifestyle behaviours (14). A login is required to access this section.
* Linkages between information provision and treatment access through a series of validated, self-report assessments, directing consumers to the best program for their symptoms (login).
* A clinician interface that permits linkage with consumers, and access to the above (login).

### 2.1.1 The eCliPSE Portal

eCliPSE (electronic Clinical Pathways to Service Excellence) is an online clinical portal developed by CIs Kay-Lambkin and Teesson in partnership with NSW Ministry of Health to facilitate access to evidence-based eHealth treatments for mental health and alcohol/other drug use problems. These disorders dominate the top 10 causes of disease burden in young Australians and lead to significant lifetime burden. This project aims to implement, scale, and cost eCliPSE, using the best methods to upscale and embed evidence-based treatment for “comorbidity” in health settings, using the best quality methodology, informed by a comprehensive, scientific implementation model developed by our study team. One in four people experience a mental health problem in any 12-month period that is severe enough to warrant treatment, and many experience concurrent alcohol/other drug use problems (a phenomenon known as “comorbidity”). Despite growing recognition of comorbidity, an increasing evidence-base of effective treatments, and an estimated annual investment of $3.2 billion (15), current treatment efforts are suboptimal, fragmented, and unscaled. In addressing this issue, the eCliPSE project will focus on two critically important, known, but neglected, evidence-practice gaps in the health service landscape:

(a) *Failure to address* *comorbidity*: Fewer than 25% of people with comorbidity access treatment, an unacceptably low rate particularly when compared with physical disorders (80% treatment coverage, 2). Despite isolated examples of good practice, only 7% of people with comorbidity will receive treatment for both problems. Mental health and alcohol/other drug use problems are traditionally approached in isolation, making significant inroads in early intervention and treatment virtually impossible (16).

(b) *Failure to optimise eHealth*: A strong body of evidence indicates that eHealth programs provide an effective treatment option for a range of mental health and alcohol/other drug use problems (2, 17) that is highly cost-effective (18, CI Christensen). The work of CIs Kay-Lambkin, Teesson, and Christensen has been the first in the world to demonstrate efficacy of eHealth interventions in the treatment of comorbidity (2, 3). Yet there are no clear models for their integration into clinical care, and Australian clinicians significantly underutilise eHealth approaches in their clinical practice (19). Important opportunities for service transformation are being missed.

### 2.1.2 Pilot Testing

 **2.1.2.1 Pilot Testing of eCliPSE**

Pilot testing of eCliPSE occurred in 2017, with 110 clinicians in MH and AOD services in the South Western and Murrumbidgee LHDs in NSW. eCliPSE training sessions were implemented with these clinicians to familiarise them with the eCliPSE tool. Following training, clinicians were asked to refer their consumers to the eCliPSE tool as indicated. No marketing beyond this strategy was employed. Assertive communication via email, and a follow-up visit has occurred between the eCliPSE team, individual clinicians, and clinical leaders in each LHD. Despite this, uptake of eCliPSE via clinician referral has been low, with 19 consumers referred to the tool over 6 months. The top 3 barriers to using eCliPSE cited by clinicians are (1) workload and time pressures, (2) that clinicians kept forgetting to refer to the tool, and (3) a perception that consumers did not need the tool (in contrast to what is known about the prevalence of comorbid MHAOD in clinical and community-based settings). Consistent with this, our previous research in a publicly-funded AOD service demonstrated that, despite clinicians only offering online evidence-based treatment to 34% of their consumers, when surveyed, the majority (80%) felt that if they were offered access, they would definitely utilise it (20). No differences between LHDs, or MH or AOD clinicians has been observed. The need for structured, supported implementation approaches with MH and AOD clinicians is indicated, as are alternatives to clinician-brokered access to the eCliPSE tool.

By way of comparison, google analytics provides a snapshot of access to eCliPSE in each LHD by consumers not referred by the target MH and AOD services. The eCliPSE tool has had 4,130 hits since July 2017. This has translated into 519 sessions by people visiting the website, and 351 unique users. These data highlight that a significant number of people experiencing MHAOD comorbidity are not seeking treatment from traditional treatment services in their LHD and point to the need for a broader approach to implementation of eCliPSE.

**2.1.2.2 Pilot Study Investigating Experiences, Attitudes and Perspectives on eHealth Innovations**

Since the testing of eCliPSE in 2017, uptake of this tool via clinician referral has been low, with the top 3 barriers to using eCliPSE cited by clinicians as being: i) workload and time pressures, ii) that clinicians kept forgetting to refer to the tool, and; iii) a perception that consumers did not need the tool (in contrast to what is known about the prevalence of co-morbid mental health and AOD use in clinical and community-based settings). The overarching eCliPSE project therefore aims to implement, scale, and cost eCliPSE, using the best methods for upscaling and embedding evidence-based treatments for mental health and AOD comorbidity in health settings.

To address this, we are currently completing a pilot study to identify the best methods for upscaling and embedding eCliPSE, an evidence-based treatment for co-morbid mental health and AOD problems, into health and community settings. This study will provide critical foundational knowledge to support this process and the proposed RCT. Using a mixed-methods approach, we are investigating the experiences, attitudes, and perspectives of mental health and AOD clinicians, practice managers and service users in the Hunter New England Local Health District (HNELHD) in relation to new eHealth innovations.

## 2.2 Objectives

The aim of this study is to evaluate the uptake of an online tool (eCliPSE) designed to improve the symptoms of mental health and alcohol/other drug use problems in people experiencing comorbidity. We will compare a direct-to-consumer (DtC) marketing strategy and an Integrated Translation and Engagement Model (ITEM) of implementation designed to engage ‘users’ (i.e. consumers & health services) with the eCliPSE tool. It is hypothesised that:

* 1. The general community experiencing MHAOD comorbidity will use the eCliPSE tool, and that these users will report improvements in their symptoms as a function of eCliPSE uptake.
	2. The DtC content marketing strategy launched in the eight local health districts (LHDs) across NSW will raise awareness of eCliPSE and in encourage uptake and use of the tool.
	3. In the four LHDs receiving ITEM+DtC, uptake of eCliPSE will be significantly greater than in the four LHDs that receive DtC only.
	4. Healthcare services implementing the eCliPSE tool in their routine service provision will report an enhanced capacity to deliver evidence-based interventions for MHAOD comorbidity.
	5. The ITEM+DtC strategy will be cost-effective compared to DtC alone.

## 2.3 Study Design

This study will be a 3-level cluster randomised controlled trial comparing uptake of and outcomes for eCliPSE across consumers, services, and LHDs receiving DtC alone versus ITEM+DtC. Endorsement has been obtained by the NSW Ministry of Health for participation of all NSW LHDs in this project. Expressions of interest will be sought from NSW mental health and/or substance use services within these LHDs and implementation will proceed as per Table 1. Of the 15 NSW LHDs, eight will be assigned to DtC and seven will be assigned to ITEM+DtC. Two mental health and alcohol/other drug services will participate in a service audit with the eCliPSE research assistant at annual intervals throughout the project. This audit assesses the capacity of the service to offer treatment for comorbid MHAOD. People with comorbid MHAOD disorders will be recruited via one of two ways: the first way is via the participating MH and AOD services, and the second way is via a targeted Direct-to-Consumer Marketing Strategy initiated by CIs from the University of Newcastle’s Business (Marketing) School.

Additionally, an exploratory qualitative and survey component will run alongside the RCT (see Figure 1) to explore participants’ views and experiences of eHealth interventions, the research and the implementation processes. Employing qualitative methods alongside a trial facilitates understanding of complex social phenomena and enables researchers to better determine the acceptability and feasibility of research methods and recruitment strategies. These components will be comprised of:

* An engagement and sustained usage survey during Phase 1 and Phase 4 of the DtC
* Focus groups with people experiencing mental health and alcohol/other drug issues who are active members of our partner organisation Beyond Blue’s ‘Blue Voices’ online community to explore perceptions of communication in online content and eHealth services

**Table 1 – Timeline for proposed study**

|  |  |  |
| --- | --- | --- |
|  | **2021** | **2022** |
| **Jan-Mar** | **Apr-Jun** | **Jul-Sep** | **Oct-Dec** | **Jan-Mar** | **Apr-Jun** | **Jul-Sep** | **Oct-Dec** |
| LHD1 1 - 7 | ITEM2 Phase 1DtC3 Phase 1-2DDCAT4 | ITEMPhase 1DtCPhase 1-2  | ITEM Phase 2DtC Phase 3 | ITEM Phase 2DtC Phase 3 | ITEM Phase 3DtC Phase 4  | ITEM Phase 3DtC Phase 4 DDCAT | Data analysis | Reporting and pub prep |
| LHD 8 - 15 | DtC Phase 1-2DDCAT | DtCPhase 1-2  | DtC Phase 3 | DtC Phase 3 | DtC Phase 4  | DtC Phase 4 DDCAT |
| Qual. and Survey Research | Phase 1 surveyFocus groups | Focus groups cont. |  |  |  | Phase 4 survey | Data analysis | Reporting and pub prep |

1Local Health District, 2Integrated Translation and Engagement Model, 3Direct-to-Consumer Marketing Strategy,4Dual Diagnosis Capability in Addiction Treatment (DDCAT)/Dual Diagnosis Capability in Mental Health Treatment (DDCMHT, 25, 26) audit tool.

**Figure 1 – Diagram of Randomised Controlled Trial and Concurrent Activities**



# 3 RANDOMISED CONTROLLED TRIAL METHODS

## 3.1 Study Setting

This study will be conducted through a total of thirty MH and AOD health services across all fifteen NSW LHDs (i.e., two MH and AOD health services per LHD) in New South Wales.

## 3.2 Eligibility Criteria

### 3.2.1 Inclusion Criteria

Eligibility of MH and AOD health services is dependent on service managers and clinicians’ willingness to participate in the proposed research project and to follow the procedures outlined in the Participant Information Statement and Consent Form (as per Table 1). Individuals utilising participating health services will be recruited separately. Inclusion criteria for service users are willingness to participate in the current research and residing in the respective LHD catchment area.

### 3.2.2 Exclusion Criteria

If any of the criteria listed under 3.2.1 are not met.

## 3.3 Interventions

NSW LHDs will be randomly assigned to receive intervention DtC (n=8 LHDs) or intervention ITEM+DtC (n=7 LHDs).

### 3.3.1 Access to Intervention

The four phases of ITEM will be administered directly into the MH and AOD health services by the research team. Leveraging Cis with direct LHD connections and our endorsement from the NSW Ministry of Health, expressions of interest will be sought from MH and AOD services across NSW to participate in this study (Appendix 1). Liaison will occur between CIs, LHDs and interested MH and AOD services. Interested services will be provided with an organisational information statement (Appendix 2) and consent form (Appendix 3) to be signed on behalf of the organisation.

### 3.3.2 Delivery of Intervention

The DtC strategy will be delivered in four phases and will occur entirely online as described in section 3.4.1. The ITEM model will be delivered in three phases and will occur through regular scheduled visits to the participating organisations described in section 3.4.1.

### 3.4 Content of Intervention

**3.4.1 Direct-to-Consumer Marketing Strategy (DtC) of Implementation**

A DtC strategy promoting the availability and functionality of the eCliPSE tool will occur via targeted social media campaigns in each of the fifteen LHDs. This strategy seeks to **build awareness, recognition, and trust of eCliPSE to encourage consumers with MHAOD comorbidity to engage with all aspects of the eCliPSE online tool**. This four-phase strategy (see tables below) uses an inbound marketing methodology to firstly attract prospective service users to the eCliPSE site (Phase 1 and 2), to convert these prospective service users to uptake eCliPSE (complete self-assessments, create a login, Phase 3) and encourage non-regular website visitors to uptake and engage better with eCliPSE and assess sustained usage of the eCliPSE tool by registered service users (Phase 4). Inbound marketing strategies rely on the creation and delivery of relevant, targeted content, direct to the consumer, and uses search engine optimization and social media marketing to ensure that this content is specific, valued, and delivered at the right place, and at the right time for the service user. Drawing on the expertise of CI Carlson and AI Wyllie in social media engagement (21) and MH social media use (22), the DtC strategy uses a range of social media marketing strategies designed to ‘funnel’ consumers into a desired behavior (e.g., uptake eCliPSE and access the available MHAOD eHealth programs). Inbound marketing techniques frequently employ ToFU (top of the funnel), MoFU (middle of the funnel) and BoFU (bottom of the funnel) techniques to achieve this outcome. Inbound marketing is the most effective marketing strategy for attracting customers to digital businesses (23) and will be applied to a MHAOD online service (eCliPSE) for the first time in this application. We will actively work with **our partner organisation** *Beyond Blue* to engage their extensive networks and media contacts to facilitate recruitment and social media support of eCliPSE, as well as NSW Ministry of Health linkage with services via CIs Haber, Morley, and Baillie.

The anticipated structure and content of the DtC is provided below. However, this is subject to change based on the rural local health districts that are eligible and used in this study and the level of technological and social media readiness and usage of these districts.

**Phase 1: ATTRACT CONSUMERS TO eCliPSE** by creating high quality, targeted, and useful content for people experiencing MHAOD comorbidity. This includes the redevelopment of website page content, updating exiting eCliPSE fact sheets and self-help tools, and creating brand new content pieces including eBooks, videos, blogs, and other free, useful content (i.e. infographics) that can be disseminated on social media to encourage prospective eCliPSE service users to visit the eCliPSE website for more detail. Phase 1 will thus involve engaging individuals with MHAOD comorbidity to generate an understanding of how to make eCliPSE more engaging and ‘search engine friendly’ for people with MHAOD comorbidity, as well as informing ToFU, MoFU, and BoFU strategies (Phases 2-4).

|  |  |
| --- | --- |
| **Activity** | **Summary of Activity** |
| Design of Consumer Profile | Focus groups will be run to help inform decisions around the creative content (i.e. eBooks, infographics), website and perceptions of eHealth social media use. Five focus groups (with up to 10 participants in each) will be recruited using different age and demographic profiles relevant to the target LHDs and people with MHAOD comorbidity.  |
| Creative Content Development | The varying types of creative content developed will be shaped by the consumer profile focus groups and phases 2-4 of the DtC strategy. Both easily digestible (Phase 2) and in-depth content (Phase 3 and 4) will be created (e.g., videos, eBooks, static content images, fact sheets, mp3 recordings, planning journals, social media messages).  |
| Website Interface Optimisation  | To optimise organic growth and search engine optimisation (SEO) of the eCliPSE portal, inclusion of creative content on eCliPSE website and linking this content to key search terms and other websites about MH and AOD will be required. This will drive site visitor traffic to the eCliPSE website |
| Create Facebook and Ad Account | Implementation of the DtC strategy will require an eCliPSE Facebook & Ad account. This will also facilitate collection of campaign metrics.  |
| Assessment & Optimisation of Creative Content | Once developed, all creative content will be pre-tested using a general population sample not residing in any of the participating LHDs.  |

**Phase 2: TOP OF THE FUNNEL [ToFU] INITIAL ‘PILLAR CONTENT’ AMPLIFICATION** This phase involves ‘funnelling’ prospective service uses to the eCliPSE website by focusing on generating awareness and helping this segment of users to understand how eCliPSE can be a solution to the challenges they are experiencing regarding MHAOD comorbidity. Creative content pieces from Phase 1 (eBooks, Infographics) will be used to communicate, educate and engage these users through social media platforms including Facebook and Instagram, as well as Google Network advertising. Website redevelopment will result in site optimisation (navigation, content) and keyword integration that will improve the search engine ranking of eCliPSE and enhanced engagement of service users whilst on the website. The goal is to encourage prospective to seek out and engage with eCliPSE website.

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| --- | --- |
| **Activity** | **Content Campaign Metrics (6 Months)** |
| Initial creative content placements (advertisements placed on social media, 3mths)  | **Facebook (FB) Metrics:** reach, impressions, in ad engagement (reactions, shares), video impressions, followers**Website Metrics:** page views (filtered by the social channel), Cost Per Result (e.g. Content Download), Campaign Traffic Time on Page/pages per session, Click Through Rate (CTR), Scroll depth (HotJar)\*note, FB interfaces with Instagram, Twitter, and other social medial channels such that advertisements on FB are deployed on these other platforms and metrics recorded by FB.  |
| Adjust creative content (3mths) |

**Phase 3: MIDDLE OF THE FUNNEL [MoFU] ACQUISITION OF CUSTOM AUDIENCE** Once prospective service users have been drawn to eCliPSE through finding eCliPSE on search engines and interacting with eCliPSE’s social media content (ToFU). The goal is to encourage users to visit, stay and engage with more of the website features. Case studies, testimonials, videos, interviews, webinars, and other content developed in Phase 1 will be used to educate consumers about the value of using eCliPSE, and calls-to-action will encourage people to access non-gated information and gated programs (e.g., create a login). This phase will also involve the creation of lookalike, service user audience groups (matched on demographics, interests, and MHAOD comorbidity but outside the study LHDs) to target and test the in-depth creative content for face validity and appeal.

|  |  |
| --- | --- |
| **Activity** | **Content Campaign Metrics (6 Months)** |
| Targeted creative content placements (3mths) | **FB Metrics**: link clicks, custom audience (pixel tracking landing page visitors)**Website Metrics**: Registrations, Cost Per Result (e.g. Content Download), Campaign Traffic Time on Page/pages per session, CTR, Scroll depth (HotJar)**Email Marketing**: Open rates, CTR, Conversion Rate  |
| Adjust creative content (3mths concurrently) |
| Adjust audience and create lookalike consumer audience group (3mths concurrently) |

**Phase 4: BOTTOM OF THE FUNNEL [BoFU] TARGETING eCliPSE LANDING-PAGE NON-CONVERTERS**

This phase focuses on the conversion of the custom and organic service user audiences who have accessed the eCliPSE website but have not created an eCliPSE registration. These non-converting service users will be funnelled into a retargeting campaign via the eCliPSE social media platforms. Specific marketing tools such as marketing automation, lead nurturing, and social media monitoring will facilitate this process. This phase will also integrate an engagement and sustained usage survey of registered eCliPSE users, to analyse the quality of the experiences with the eCliPSE website and respective programs. Understanding drawn from this study will enable the identification of the drivers of engagement and sustained use of this eHealth service.

|  |  |
| --- | --- |
| **Activity** | **Content Campaign Metrics (6 Months)** |
| Targeted creative content placements (3mths) | **FB Metrics:** total conversions by group, cost per conversion**Website Metrics**: Registrations, Cost Per Result (e.g. Content Download), Campaign Traffic Time on Page/pages per session, CTR, Scroll depth (HotJar)**Email Marketing**: Open rates, CTR, Conversion Rate  |
| Adjust creative content (3mths) |
| Engagement and Sustained Usage Survey | Registered eCliPSE users, who have been engaged and using the programs will be contacted via the customer relationship management (CRM) system to participate in an engagement and sustained usage study.  |

**3.4.2 Integrated Translation and Engagement Model (ITEM)**

Developed by CIs Heinsch and Kay-Lambkin, in collaboration with CIs Haber, Morley, Baillie, and AI Shaw, an evidence-informed ITEM will guide the implementation of eCliPSE in seven of the fifteen LHDs. In contrast to the pilot of eCliPSE, the ITEM is based on the latest evidence for effective implementation, synthesising different approaches into a coherent, integrated model. It synthesises evidence on facilitators and barriers to translation and focuses on the various disorderly interactions between researchers and users at different stages of knowledge production, dissemination, and utilisation (24). It will engage consumers, clinicians, service leaders and policy makers in all stages of implementation, with additional proactive support for ongoing implementation provided on site throughout the trial. Our clinical CIs (Haber, Morley, Baillie) are critical in providing the credibility, impetus, and time for staff to actively engage with the tool and ITEM (described below).

**PHASE 1: ENGAGEMENT, KNOWLEDGE EXCHANGE AND CO-DESIGN (6 months)** Engagement and relationship-buildingkey stakeholders to create a strong foundation for the translation of eCliPSE into local health services. Knowledge exchange and co-design with health services will identify i) gaps and opportunities for service provision, ii) capacity to treat MHAOD comorbidity, and iii) facilitators and barriers to translation. These will shape phase 3 activities.

|  |  |  |
| --- | --- | --- |
| **Activity** | **Evidence** | **Interaction Models** |
| **Convene** an eCliPSE Translation Team (n=6-8) to drive the implementation of eCliPSE in DtC+ITEM LHDs  | Partnerships between researchers and users will facilitate research uptake in practice (25). | **Translational model** emphasises using multiple constituents within the research pipeline as a means of converting basic knowledge into practice (26) |
| **Engage** in relationship building and deconstruction of dynamics through open discussion about attitudes, assumptions and values about research/practice.  | Informal, personal contact minimises power differentials between researchers and users (27, 28). | **Interaction** **model** assumes that the extent and quality of engagement, and the fit with personal values and beliefs, will improve implementation (28).  |
| **Assess** - use baseline DDCAT/DDCMHT assessments to identify gaps and opportunities in service provision for MHAOD comorbidity. | Health care environments are complex and assessing the setting prior to engaging in translation activities should be the first step (29). | **Linkage & Exchange**models facilitate collaboration between researchers and decision makers (27). |
| **Shape** the implementation of eCliPSE (phase 3) with the Translation Team in line with the above assessments. | Co-production leads to the production of relevant, useable knowledge for practice (30). | **Co-production** frameworks inspire knowledge translation through genuine co-development (31). |

**PHASE 2: IMPLEMENTATION AND SUPPORT (6 months)** of eCliPSE will occur to bridge cultural barriers to uptake and encourage seamless integration of the tool across services.

|  |  |  |
| --- | --- | --- |
| **Activity** | **Evidence** | **Interaction Models** |
| **Introduce** eCliPSE employing a ‘trigger encounter’ (example role play encounters) to enhance engagement with eCliPSE.  | Translation is enhanced through ‘trigger encounters’ that are informal, personal, and engender an emotional response (28). | **Interaction model** assumes that the extent and quality of engagement, and the fit with personal values and beliefs, will improve use (32). |
| **Train** practitioners in the use of eCliPSE (minimum of 4 2-hour sessions in each LHD). | Uptake is enhanced when information provision and training occurs in a clear, user-friendly way (33), which emphasises implications and relevance for practice (34).  | **Two communities** theory assumes a cultural difference between researchers and policy makers that hinders communication and prohibits knowledge utilisation due to a lack of shared norms, priorities and languages (35).  |
| **Provide support** by:* 1. Training to enhance practitioner confidence, and to understand key terms/processes.
	2. Addressing any concerns or defensiveness
	3. Engaging in regular, active interaction.
 | Uptake is enhanced when practitioner confidence and experience in engaging with technology is addressed (36). Positive engagement occurs when user defensiveness is engaged directly (28). |

**PHASE 3: SUSTAINABILITY AND ORGANISATIONAL CHANGE (6 months)** ‘Champions’ will be identified to support implementation and advocate for organisational recognition of activities. This will establish a strong foundation for sustained implementation.

|  |  |  |
| --- | --- | --- |
| **Activity** | **Evidence** | **Interaction Models** |
| **Establish** adequate supports and mentoring within the practice setting to achieve effective, sustained implementation of eCliPSE. | Leadership in the form of a designated champion to mentor practitioners in implementing evidence has been identified as a facilitator for research use (28). | **Organisational learning** model accounts forthe impact of organisational processes on knowledge utilisation (24). |
| **Advocate** for organisational change to enable and support sustained implementation and avoid top-down translation. | Implementation activities that are formally recognised and supported as a priority area within the organisation are more likely to be sustained (37). This includes ensuring sufficient time on the job to implement new ideas/evidence (38) and to discuss research with colleagues (33). |
| **Assess** – use DDCAT/DDCMHT to compare initial audit of service provision. | Organisational and behavioural change has found to be effective when audit and feedback are provided as a stimulus (29). | **Linkage & Exchange**models facilitate collaboration between researchers and end users (27). |

## 3.5 The DDCAT/DDCMHT Audit

The Dual Diagnosis Capability in Addiction Treatment (DDCAT) and Dual Diagnosis Capability in Mental Health Treatment (DDCMHT) indexes (39) help organisations assess their capacity to provide treatment for people diagnosed with a mental illness who also have a co-occurring substance use disorder. The DDCAT/DDCMHT audits will be completed, as described in section 3.4.2, during Phase 1 and Phase 3 of the ITEM model. The DDCAT/DDCMHT use observational methods to gather information about a service and rate its capability. Researchers acting as external raters will make site visits during Phase 1 and Phase 3 to collect data about the program from a variety of sources, including:

1. Ethnographic observations of the milieu and physical settings;
2. Open-ended interviews with managers and clinicians, and surveys with service users; and
3. Review of documentation such as medical records, program policy and procedure manuals, brochures, daily patient schedules, telephone intake screening forms, and other materials that may seem relevant

The DDCAT/DDCMHT begins will identifying the appropriate contact person, likely a service manager, and in preliminary conversations, to define the scope of the assessment and clarify the time allocation requirements.

## 3.5.1 Ethnographic Observations

As per the DDCAT/DDCMHT indexes, ethnographic observation is required to gather information about a service and rate its capability. This observation is designed to be brief and to get a sense of the social environment. The observation that will occur as part of this research study will only be conducted in common spaces of participating services. No observation will occur with practitioners while they are engaging with a client either in-person or remotely. When arranging the activities of the DDCAT/DDCMHT with the contact person for the service, details of what is involved will be provided and managers will be asked to let their staff members know about the presence of a research team and to advise them that any observation is for the purpose of auditing the service, not individual practitioners.

## 3.5.2 Open-Ended Interviews and Surveys

Conducting interviews with different members of the service will allow the research team to hear different perspectives on the services practices and procedures. Directors, supervisors, clinicians, or personnel who agree to participate in audio-recorded interviews as part of the DDCAT/DDCMHT audit will be asked to read a participant information statement (Appendix 4) and provide written consent (Appendix 5). An interview schedule has been developed and can be found in Appendix 6. The interview schedule has been developed using the recommended questions for service managers and clinicians within the DDCAT/DDCMHT indexes (39).

Including the perspectives of service users is important for the DDCAT/DDCMHT audit to get a more complete picture of the service capability. Typically, service users are engaged in individual interviews for the purpose of the assessment. However, due to the scale and complexity of the broader project, we have chosen to disseminate questions to service users via online survey. Using an online survey will also further protect the identity of potential participants. An email will be sent to service users from the appropriate service manager or clinician inviting them to complete a short survey about their experience using the service. The research team will provide the service manager with the Participant Information Statement (Appendix 7) and the survey link. A list of survey questions has been developed using the recommended questions for service users within the DDCAT/DDCMHT indexes (Appendix 8).

## 3.5.3 Review of Documentation

For the DDCAT/DDCMHT, it is helpful to review a variety of documentation in order to audit the participating service. These documents will be dependent on the service, but will include medical records, program policy and procedure manuals, brochures, daily patient schedules, telephone intake screening forms, and other materials that may seem relevant. In the case of medical records and case notes, we are seeking informed consent from service users to review such documents. Participants who agree to complete the DDCAT/DDCMHT survey will also be asked for their consent to allow the research team to review their case notes from their host service. Information about this process will be provided to participant in the Participant Information Statement (Appendix 7) and Consent Form (Appendix 22). As the purpose of accessing medical records is for the service assessment, the research team will not be collecting any form of personal information or data from the accessed records. In retrieving the medical records from the participating services, the research team will obtain these from the appropriate service manager or clinician. The service manager will remove any potentially identifiable information from the records before providing them to the research team for review. Data collection will follow a data management plan (Appendix 23) and be recorded against a data collection sheet (Appendix 24).

## 3.6 Outcomes

## 3.6.1 Primary Outcome

The primary outcome of this research concerns the dissemination success of the eCliPSE tool to service users. In particular, we hypothesise that uptake of eCliPSE, as measured by the number of sign-ups to eCliPSE, will be significantly greater in the seven LHDs receiving ITEM+DtC compared to the eight LHDs receiving DtC only. The number of sign-ups to eCliPSE will be assessed for the duration of the study and will be recorded electronically via the eCliPSE platform. eCliPSE website analytics will record the location of users and new users will be asked to enter their postcode, which will inform the research team of the LHD in which new users are residing.

## 3.6.2 Secondary Outcomes

In line with our research objectives, we will be examining four additional outcomes to answer secondary research questions.

1. To examine whether engagement with the eCliPSE tool will be significantly greater in the seven LHDs receiving ITEM+DtC than in the eight LHDs that receive DtC only, we will inspect eCliPSE usage patterns. These metrics are automatically recorded by the eCliPSE backend and consist of basic count data such as number of logins to eCliPSE, the number of eCliPSE pages accessed, and the average session duration per login.
2. To examine whether service users registered to eCliPSE will report significant improvements in mental health symptoms and alcohol usage patterns over time, and whether service users located in LHDs receiving ITEM+DtC will report superior symptom alleviation compared to service users located in LHDs that receive DtC only, we will be assessing eCliPSE users’ symptom trajectories via the eCliPSE website. Specifically, eCliPSE will prompt completion of self-report instruments at first login (baseline), and at 12-weekly intervals throughout the study period. Those self-report instruments are the Depression, Anxiety and Stress Scale (DASS-21), alcohol consumption on the Opioid Treatment Index (OTI), Alcohol Use Disorder Identification Test (AUDIT), Severity of Dependence Scale (SDS), and the Assessment of Quality of Life questionnaire (AQoL-8D).
3. We predict that the ITEM+DtC strategy will be cost-effective compared to DtC alone. To test this prediction, we will examine MHAOD service staff’s productivity assessments and service users. CI Mihalopoulos will oversee the collection of detailed data on the resources to deliver each component of the interventions (DtC and ITEM), which will allow accurate costing of program delivery. Each participant’s health care service use will be assessed using Medicare (MBS) and Pharmaceutical Benefits Schedule (PBS) data. A brief Resource Use Questionnaire (RUQ) will capture resource consumption outside of MBS and PBS, adapted from existing RUQs of CI Mihalopoulos.
4. Particip

## 3.7 Sample Size

We are including all fifteen NSW LHDs in this study, two MH and AOD services in each LHD (thirty in total) with a minimum of 50 patients in each service (1500 patients using eCliPSE in total).

For the purpose of the DDCAT/DDCMHT assessment, noted in Secondary Outcome 4, we are seeking 5 clinicians and 5 service users per service (10 clinicians and 10 service users per LHD, for a total of 150 clinicians and 150 service users).

## 3.8 Recruitment

Endorsement has been obtained by the NSW Ministry of Health for the inclusion of all fifteen NSW LHDs. Expressions of interest will be sought from MH and AOD services within these LHDs, with the assistants LHD endorsement and of select CIs with direct links to the NSW Ministry of Health. Expressions of interest will be sought from eligible MH and AOD services to participate in this study.

## 3.9 Withdrawal from Study

Services may withdraw from the research study at any time. MH and AOD health services will be able to contact the research team and request for their consent to be withdrawn and any data that has been collected to this date to be permanently deleted. MH and AOD health services also have the option to cease any ongoing research involvement but allow the research team to analyse previously collected data for the stated research purposes. The withdrawal process is presented in detail in the Participant Information and Consent Form. A copy of this form is provided to participating MH and AOD health services upon registration to the study.

Community participants who register to the eCliPSE portal will be presented with an online Participant Information and Consent Form before assessing any baseline measures. The Participant Information and Consent Form can be downloaded and contains instructions on how to withdraw. Participants can withdraw their consent to participate in this research by contacting the research team. Participants can indicate whether they would like to withdraw and have all their data deleted, or whether they agree to have previously provided data analysed for stated research purposes.

## 3.11 eCliPSE Service User Consent

Registered users, both clients and clinicians of mental health and alcohol/other drug services, of eCliPSE will be explicitly advised upon registration that data collected through the website will be used as part of a research project and that their agreement is needed to continue. Upon registration, users will be advised that their personal information will remain completely anonymous. Registered users will be advised that by submitting their registration form, they are agreeing to participate in the project with research data collection outlined in the registered user participant information statement (Appendix 9) which they will be directed to read upon registering. A visual example of what will be included in the registration form can be found in Appendix 10, based on the registration of online program The Ripple Effect.

## 3.11 Assignment of Interventions

### 3.11.1 Allocation

The unit of randomisation in this research will take place at the LHD level. Stratification by geographical area will be employed by which the regional/remote and metropolitan LHDs will be split between the two conditions.

### 3.11.2 Blinding

Researchers, health service staff, and community participants will not be blinded to conditions. However, once assigned, researchers will avoid descriptions of other study arms to decrease awareness among participating MH and AOD health service staff and community participants of the existence of a second study condition. Additionally, MH and AOD health services allocated to either DtC or ITEM+DtC will receive separate versions of the Participant Information and Consent Form outlining procedures relevant only to their respective study condition.

## 3.12 Data Collection, Storage and Analysis

### 3.12.1 Data Collection

The specific data collection methods pertaining to each individual outcome of this study have been stated in section 3.5 of this document.

### 3.12.2 Data Storage

All information and data collected throughout this research study will be stored in accordance with the University of Newcastle’s safe data storage requirements. Soft copy documents will be stored using the protected data storage solution OneDrive. Hard copy documents will be scanned and saved to OneDrive before being securely destroyed. Service user registration and questionnaire completion will be secured stored and maintained electronically via the eCliPSE password protected web platform. Data will only be accessible by the research team and will be stored for a minimum of five years.

### 3.12.3 Data Analysis Methods

To address to primary outcome of this study, eCliPSE website analytics will be converted into an overall index of engagement with the tool, and this index will be compared between LHDs receiving ITEM+DtC versus DtC alone. The eCliPSE website analytics are geotagged, such that data are reliably associated with a region within an LHD. CI Sunderland will lead this analysis.

To address the subsequent secondary outcomes, respectively, the following analysis will be conducted:

1. CI Carlson and AI Wyllie will oversee the collection of data on consumer profiles, content data analytics, data assessment and optimisation of creative content within eCliPSE. Data will be analysed through qualitative approaches, metrics, and multivariate analysis through software IBM SPSS v.25. Increases in FB and website metrics indicative of uptake/engagement with eCliPSE will be examined across DtC phases 2-4.
2. CI Sunderland will lead the analysis of self-reported symptoms by all eCliPSE users over time (minimum of 100 per LHD, 1500 in total). Using the eCliPSE uptake data, an index of engagement will be generated and used to explore symptom change across different users with different levels of eCliPSE use. Overall change is DASS21, OTI, and AUDIT scores across time points will be modelled using multilevel latent growth models with time nested in consumers, and consumers nested in LHDs. As standard practice, the functional form of change in the model will be examined by fitting preliminary curves with different polynomials of time to represent linear and non-linear change.
3. CI Mihalopoulos will oversee the collection of detailed data on the resources to deliver each component of the intervention (ITEM and DtC) which will allow accurate costing of program delivery. Each participant’s health care service use will be assessed through the use of Medicare (MBS) and Pharmaceutical Benefits Schedule (PBS) data. A brief Resource Use Questionnaire (RUQ) will capture resource consumption outside of MBS and PBS, adapted from existing RUQs of CI Mihalopoulos. Standard Australian unit costs from published sources will be applied. The primary analysis will be conducted from a societal perspective with an additional analysis from a health sector perspective. Cost-effectiveness of ITEM+DtC will be compared to DtC alone through a series of incremental cost ratios known as cost-consequences analysis. This involves calculating the mean difference in total costs divided by the mean difference in depression, anxiety, and stress scores from the DASS21 and the OTI, as well as quality adjusted life years (QALYs) calculated from the AQoL-8D. Standardised economic evaluation techniques including bootstrapping to determine confidence intervals will be used in the evaluation. Modelling will estimate costs/outcomes that may accrue beyond the initial trial and to estimate the cost-effectiveness and budget impact of the interventions if implemented across Australia.
4. DDCAT/DDCMHT scores will be examined over time for i) MH and AOD services within an LHD, ii) MH services between DtC alone LHDs and ITEM+DtC LHDs, and iii) AOD services between DtC alone LHDs and ITEM+ DtC LHDs. Following the methodology of Matthews (40), a minimum of 5 MH staff members and 5 AOD staff members in each LHD will take part in the DDCAT/DDCHMT at each audit timepoint, along with a minimum of 5 MH and 5 AOD clients of each services in each LHD. Ten clinical files in each MH and AOD service in each LHD will be selected for the audit and will also contribute to the assessment. Program manuals, policy, and procedural manuals will also be reviewed. Following each audit, each MH and AOD service is given an overall capability rating on a 5-point scale. CI Sunderland will lead this analysis, non-parametric test, and two-tailed analyses to reduce type-1 error rates and for non-normal distributions resulting from the small sample size.

## 3.13 Monitoring

### 3.13.1 Data Monitoring

 As this is intended as an exploratory study, no interim analysis for efficacy will be performed.

### 3.13.2 Harms/Adverse Events

It is not anticipated that the interventions will result in any harms or adverse events for either the participating health services or service users. Should any adverse events occur as a result of service users accessing the eCliPSE portal or completing routine self-report instruments, eCliPSE will facilitate access to evidence-based eHealth treatments, support services and information. Additionally, those registered with eCliPSE through this study are likely to be engaged in MH and AOD health services to provide independent clinical support.

### 3.13.3 Auditing

Not to be confused with the DDCAT audit outlined in section 3.5.2 of this document, there is no intention for auditing the conduct of this trial.

# 4 MARKETING RESEARCH: QUALITATIVE AND SURVEY METHODS

The qualitative and survey components of the overall study are designed to complement the randomised controlled trial detailed in the protocol above.

## 4.1 Study Setting

The qualitative and survey components will be conducted through the Priority Research Centre for Brain and Mental Health Research and the University of Newcastle’s Business (Marketing) School. Focus groups will be conducted electronically via Zoom/Skype software in keeping with current COVID-19 restrictions.

## 4.2 Eligibility Criteria

### 4.2.1 Inclusion Criteria

 For both the online survey and focus groups, participants must:

* Be aged 18 years and older
* Be diagnosed with a mental health and/or alcohol/other drug issues
* Be either an active member of the Beyond Blue ‘Blue Voices’ online community *or* an active member of eCliPSE

### Exclusion Criteria

For both the online and focus, participants must not:

* Be aged 17 years or younger

## 4.3 Online Survey

An online survey will be conducted during Phase 1 and Phase 4 of the DtC model. The purpose of the survey in Phase 1 is to understand how service user experiences with eHealth social media communities affect their attitudes and behaviours towards these services. Whilst the purpose for the online survey in Phase 4 is to assess eCliPSE service user engagement and sustained usage of the eCliPSE portal through the RCT.

The survey conducted during Phase 1 will focus on the non-eCliPSE users, recruited from the Beyond Blue ‘Blue Voices’ online community as well as the broader community. Those who are interested in participating will be provided with a participant information statement and a link to the online survey. The content of the Phase 1 survey can be found in Appendix 11. The survey conducted in Phase 4 will seek participants of the registered users of eCliPSE through the RCT. An email will be sent through the eCliPSE CRM email campaign software. Registered users will be emailed the participant information statement and a link to the online survey. The content of the Phase 4 survey can be found in Appendix 12.

## 4.4 Focus Groups

Individuals experiencing mental health and/or alcohol/other drug issues will be invited to participate in one of five focus groups to be conducted by a member of the research team during Phase 1 of the DtC. The purpose of the focus groups is to explore individuals’ perceptions of the quality of the online communication content of health and eHealth services and the types of interactions that they have with these services via social media platforms. Additionally, the focus groups will be used to explore the necessary features of eHealth services, social media and website platforms that enhance user’s engagement. It is not expected that any questions posed to the individuals will cause any emotional distress. The focus groups will take place via Zoom/Skype technology ad will take approximately 60 minutes to complete. The focus groups will be audio-recorded for transcription and analysis. A focus group moderators guide has been developed and can be found in Appendix 13. Additionally, participants will be asked to complete a brief demographic survey, which can be found in Appendix 14.

## 4.5 Sample Size

*Surveys*: A calculated sample size of 1000 participants is required across both surveys (n = 500 per survey) in order to have sufficient power analysis that produces results with a high degree of confidence and precision, as well as mitigating sampling error.

*Focus groups*: A sample of 50 participants will be sought for five focus groups (n = 10 participants per focus group).

## 4.6 Recruitment and Consent

*Surveys*: Participants for the survey conducted in Phase 1 of the DtC will be recruited via expressions of interest from the Beyond Blue ‘Blue Voices’ online community, via social media pages and within the CI/partner team. Recruitment advertisements (Appendix 15) will be launched on the ‘Blue Voices’ community forum, eCliPSE social media platforms and website. Those who are interested will be contacted by a member of the research team and will be provided with a participant information statement (Appendix 16) and a link to the online survey hosted by Qualtrics. It is considered that implied consent will be provided once the participant chooses to commence the survey.

Participants conducted in Phase 4 of the DtC will be recruited via expressions of interest from eCliPSE registered users through the eCliPSE CRM email campaign software (Appendix 17). Registered users will be emailed the participant information statement (Appendix 18) and a link to the survey hosted by Qualtrics. It is considered that implied consent will be provided once the participant chooses to commence the survey.

*Focus groups*: Individuals who are aged 18 years and over, who are diagnosed or self-diagnosed with a mental health and/or alcohol/other drug issue and are active members of the Beyond Blue ‘Blue Voices’ online community will be invited to participate in this study. Recruitment advertisements (Appendix 19) will be launched on the ‘Blue Voices’ community forum. Those who are interested in participating will be contacted by a member of the research team to confirm eligibility and invited to attended one of the allocate focus group sessions. Participants who are ineligible to participate in the study will receive follow up contact by a research and thanked for their interest. Participant information statements (Appendix 20) and consent forms (Appendix 21) will be emailed to participants prior to the focus groups. Prior to commencing the focus groups, written consent will be obtained, and a demographic questionnaire will be completed.

## 4.7 Withdrawal from Study

Participants are free to withdraw at any time of the study, including during the focus groups, up until the point of data analysis. Participant’s decision to participant or withdraw from this study will not be shared with any mental health and/or alcohol/other drug organisation they may have a relationship or affiliation with.

## 4.8 Data Storage and Analysis

###  4.8.1 Data Storage

All information and data collected throughout this research study will be stored in accordance with the University of Newcastle’s safe data storage requirements. Soft copy documents will be stored using the protected data storage solution OneDrive. Hard copy documents will be scanned and saved to OneDrive before being securely destroyed. Service user registration and questionnaire completion will be secured stored and maintained electronically via the eCliPSE password protected web platform. Data will only be accessible by the research team and will be stored for a minimum of five years.

###  4.8.2 Data Analysis

*Surveys*: The Phase 1 and Phase 4 online surveys will undergo rigorous validity and reliability testing, followed by an analysis of the structural model to assess the variance explained (R2) in the framework, which is a key criterion for assessing the quality of a structural model (41). Partial least squares equation modelling (PLS-SEM) via SmartPLS v.3.2.8 will be used to test the series of relationships of the frameworks and respective constructs being tested across both Phase 1 and Phase 4.

*Focus groups*: Transcription of the audio-recordings will be performed by a researcher and data recordings will be handled confidentially and securely, with encryption for all the audio as per the University of Newcastle’s data storage requirements. Thematic analysis will be used to analyse the focus group data. Using Braun and Clarke’s (42) six-step method, a process of identifying patterns and themes within the qualitative data will be applied. These steps include: i) familiarising oneself with the data; ii) generating initial codes; iii) searching for themes; iv) reviewing themes; v) defining and naming themes; and vi) producing the report. Analysed data will inform the development of both the creative content pieces and the eCliPSE website redevelopment as part of the DtC strategy.

# 5 ETHICS AND DISSEMINATION

## 5.1 Research Ethics Approval

Research ethics approval will be sought from the Hunter New England Local Health District Human Research Ethics Committee (HNELHD-HREC). A site-specific approval will be sought from the Hunter New England Local Health District Research Governance Office.

## 5.2 Protocol Amendments

This study will be conducted according to the current protocol version. Any changes to the conduct of the study or the study documentation that affects the scientific intent, study design, patient safety, or may affect a participant’s willingness to continue participating in the study will be considered an amendment. Amendments to this protocol will be submitted to the HNELHD-HREC and changes to the conduct of the study only instituted after approval is granted.

## 5.3 Consent

Informed consent will be sought from all participating MH and AOD health services, as well as participating service users who register with eCliPSE. Consent may be withdrawn, either by health services or service users, at any time during the study. If this occurs, the research team will confirm with the health service or service user whether they would like all data collected up until this point withdrawn, or whether they are happy for this data to remain part of the study. For service users, withdrawing consent will have no effect on the clinical care provided to them via the MH and AOD health service they are enrolled in.

## 5.4 Confidentiality

Enrolment in the study and use of the eCliPSE portal, either by health services or service users, will not be shared among other users. The only exception to this would be in the case where a health service clinician and service user discuss the use of eCliPSE in the context of clinical care. All identifiable and personal information obtained via registration to eCliPSE or through the completion of consent forms will be securely stored and will only be accessible by members of the research team. No identifiable or personal information of either health services or service users will be included in the results of this study which will be disseminated as detailed in section 4.8.

## 5.5 Declaration of Interests

None of the study team members have a financial or other material interest in the outcome of the research.

## 5.6 Access to Data

Only members of the study team will have access to the study data.

## 5.7 Ancillary and Post-trial Care

As standard MH and AOD health care is provided to all participants via their participating health service, any follow up care as determined clinically appropriate will be provided by the responsible service or clinician.

## 5.8 Dissemination Policy

Findings may be presented in academic publications, journals or conferences; however, individual participants will not be named or identified in any reports or resources arising from the project. Non-identifiable data may be shared with other parties to encourage scientific scrutiny and to contribute to further research and public knowledge, or as required by law.

# 6 APPENDICES

6.1 Organisational Expressions of Interest

6.2 Organisational Information Statement

6.3 Organisational Consent Form

6.4 DDCAT/DDCMHT Clinician Interview Participant Information Statement

6.5 DDCAT/DDCMHT Clinician Interview Participant Consent Form

6.6 DDCAT/DDCMHT Clinician Interview Schedule

6.7 DDCAT/DDCMHT Service User Survey Participant Information Statement

6.8 DDCAT/DDCMHT Service User Survey Questions

6.9 eCliPSE Service User Information Statement

6.10 Example Online Registration Form

6.11 Phase 1 Survey Questions

6.12 Phase 4 Survey Questions

6.13 Focus Group Moderators Guide

6.14 Focus Group Demographics Survey

6.15 Phase 1 Survey Advertising Material

6.16 Phase 1 Survey Participant Information Statement

6.17 Phase 4 Survey Email Recruitment Template

6.18 Phase 4 Survey Participant Information Statement

6.19 Focus Group Advertising Material

6.20 Focus Group Participant Information Statement

6.21 Focus Group Participant Consent Form

6.22 DDCAT/DDCMHT Service User Consent Form

6.23 DDCAT/DDCMHT Data Management Plan for Case Notes and Records

6.24 DDCAT/DDCMHT Data Collection Sheet for Case Notes and Records

# References

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