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Prospective cohort study of the evaluation of patient benefit from the redevelopment of a complete national forensic mental health service: the Dundrum Forensic Redevelopment Evaluation Study (D-FOREST) protocol

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ABSTRACT

Introduction Secure forensic mental health services are low volume, high cost services. They offer care and treatment to mentally disordered offenders who pose a high risk of serious violence to others. It is therefore incumbent on these services to systematically evaluate the outcomes of the care and treatment they deliver to ensure patient benefit in multiple domains. These should include physical and mental health outcomes, as well as offending related outcomes. The aim of Dundrum Forensic Redevelopment Evaluation Study (D-FOREST) is to complete a structured evaluation study of a complete national forensic mental health service, at the time of redevelopment of the National Forensic Mental Health Service for the Ireland.

Methods and analysis D-FOREST is a multisite, prospective observational cohort study. The study uses a combination of baseline and repeated measures, to evaluate patient benefit from admissions to forensic settings. Patients will be rated for physical health, mental health, offending behaviours and other recovery measures relevant to the forensic hospital setting at admission to the hospital and 6 monthly thereafter.

Lagged causal model analysis will be used to assess the existence and significance of potential directed relationships between the baseline measures of symptomatology of schizophrenia and violence risk and final outcome namely length of stay. Time intervals including length of stay will be measured by median and 95% CI using Kaplan-Meier and Cox regression analyses and survival analyses. Patient related measures will be rated as changes from baseline using general estimating equations for repeated measures, analysis of variance, analysis of covariance or logistic regression.

Ethics and dissemination The study has received approval from the Research Ethics and Effectiveness Committee of the National Forensic Mental Health Service, Ireland. Results will be made available to the funder and to forensic psychiatry researchers via international conferences and peer-reviewed publications.

Trial registration number NCT05074732.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Dundrum Forensic Redevelopment Evaluation Study (D-FOREST) will provide the first comprehensive evaluation of a complete National Forensic Mental Health Service.
⇒ D-FOREST design will permit the evaluation of benefit over time for individual patients, groups of patients and the evaluation of service-based outcomes.
⇒ D-FOREST will systematically evaluate multiple domains of recovery including patients' physical health, mental health, offending behaviours and social and occupational functioning.
⇒ For self-rated or interview rated measures, it is likely that engagement will be highest among the group who are progressing best in terms of their mental health and offending therapy work, which could bias some results.

BACKGROUND

Context

Forensic mental health services have a dual role, to treat mental disorder and reduce violent recidivism.[1] Forensic mental health services are low volume, high cost services and, therefore, it is vital to conduct robust outcome measure studies to demonstrate benefit and effectiveness.[2] This paper describes the protocol for a study comprising the evaluation of a complete National Forensic Mental Health Service (NFMHS) at a time of significant change, that of the redevelopment of Ireland's NFMHS from a 19th century building to a complete national service in North Dublin. We consider that our described protocol will have significant international generalisability including for the evaluation of routine outcomes such as within state forensic mental health services of

Australia, Canada or European Union states and aspects of routine outcomes for secure services such as evidence based outcomes for Commissioning for Quality and Innovation targets for National Health Service England which link part of the payments system for healthcare providers and hospitals to demonstrable measured goals and outcomes.[3]

Current knowledge

Treating mental disorder, physical health and symptomatic recovery in secure forensic settings

Treating mental disorder is one of the two main goals of forensic mental health services, the second being treating violence. Patients in forensic settings often present with highly treatment resistant psychotic illnesses, combined with multiple comorbidities including personality disorder, for example, dissocial personality disorder or emotionally unstable personality disorder, polysubstance misuse and other issues such as traumatic childhood experiences.[1 4] Schizophrenia is typically the most common diagnosis in forensic units and patients in the Central Mental Hospital (CMH) Dundrum are no exception.[4–6] Schizophrenia is increasingly recognised as a major brain disorder with significant morbidity and mortality and a very significant burden of illness.[7 8] Excess mortality is seen across all age groups among those with schizophrenia and only 13.5% achieve recovery.[9 10] Treatment resistant psychosis (TRS), which is common in forensic settings, is becoming an area of increased focus for medical research and there may be differences in striatal dopamine synthesis capacity in those who respond to antipsychotic medications and those who go on to develop treatment resistant illnesses. Patients in secure forensic settings pose a high risk of violence towards others if their mental illnesses are not adequately managed and treated. Therefore, the ability of forensic psychiatrists to reduce doses of antipsychotics or switch to less efficacious medications is very limited.

Physical health comorbidities of schizophrenia and major mental illnesses

The physical health comorbidities of those with major mental illnesses such as schizophrenia are a greater contributor to the excess mortality gap than unnatural deaths such as suicide.[10 11] High rates of obesity, type 2 diabetes (T2D), metabolic syndrome and other illnesses contribute to the medical vulnerability of this patient group in community and forensic cohorts.[12–14] While in the past these were considered to be almost exclusively side effects of antipsychotic medication, research is now examining whether or not this theory may have been overly simplistic. The pathways between obesity and major mental illness may in fact be bidirectional, both obesity and neuropsychiatric conditions are linked to neuroinflammatory processes.[15 16] While studies have demonstrated metabolic derangements including raised body mass index (BMI), impaired glucose tolerance and dyslipidaemia in patients with schizophrenia treated with atypical antipsychotics,[17] it has also been shown that insulin resistance is found in antipsychotic naïve patients with schizophrenia.[18] There is a higher risk of T2D and impaired glucose tolerance among first-degree relatives of patients with non-affective psychoses.[19–21] The DISC1 gene which is an established risk factor for schizophrenia[22] also affects the pancreatic islet cells,[23] and other genetic risk factors for schizophrenia are also implicated in impaired glucose tolerance and T2D mellitus.[24 25]

Forensic recovery, recovery from the use of violence and rule breaking behaviours

Recovery from using violence and recovery from rule breaking behaviour are key aspects of recovery in forensic settings.[4] Violence is an unmet treatment need for each patient at the time of admission to a secure forensic mental health service. It is vital that staff members acknowledge this properly. Minimising the index offence or past violent incidents results in minimising the patient's unmet needs in this area. Minimising past violence or unmet need in this area, rather than supporting the patient, undermines the patient's ability to engage in relevant treatment programmes and desist from violence. If patients do not manage to break the cycle of violence their length of stay in secure services can be very prolonged. Successful completion of therapeutic programmes is associated with moving forward on care pathways to less secure wards, conditional discharge and also on placement on care pathways within high security hospital settings, for both patients with primary mental illness and those with primary personality disorder.[4 26 27]

Functional and personal recovery in secure forensic settings

Functional recovery in secure forensic settings is about increasing independence, resilience, stress tolerance and coping skills. Personal recovery in secure forensic settings includes areas such as developing a working alliance with the clinical team, trust and hope. Satisfaction with life and the environment are key to this piece. It has been demonstrated that working alliance and trust are meaningful concepts in secure settings and correlate with measures of the severity of positive symptoms of schizophrenia and overall functioning.[28 29]

Ireland's NFMHS encompasses a complete forensic service, and therefore offers all of the above aspects of secure care, based from one campus at Dundrum Hospital.[27] The service has been based at Dundrum since 1851, and has been a working forensic psychiatric hospital since that time, making it the oldest such site in Europe to have consistently been in use as a secure forensic hospital. Critique of the age of the buildings from bodies such as the Committee for the Prevention of Torture (Council of Europe) led to a €140 million investment in a new campus at Portrane, Dublin.[30] The complete NFMHS will leave Dundrum and move to the new campus in Portrane from 2022.

Study aims

Research hypothesis and aims

This is a prospective observational cohort study, consisting of an evaluation of patient benefit of the complete redevelopment of a NFMHS for Ireland. We hypothesise that the

redevelopment of the campus from Dundrum Hospital to a new 170-bed secure forensic hospital in Portrane will demonstrate improvements in two main areas, first service wide improvements and second patient benefit related improvements.

We hypothesise that the development of the new campus at Portrane will lead to reduced time on the waiting list for admission and reduced length of stay in the hospital as well as sustainable rates of admissions and discharges maintained over the 5-year period of this study.

We anticipate that the newly expanded hospital will be able to facilitate the admission of patients with higher security needs from the prison settings, and therefore there may be a rise in the security needs profile of the group, while urgency of need for admission on the waiting list will decrease.

We anticipate that patient engagement with group and individual therapy will improve with greater access to therapists as the staff number will expand and, therefore, measures of therapeutic programme completion and recovery and measures of risk of violence and self-harm should improve across the patient group. We also anticipate finding improved measures of patient ratings on environmental measures such as ward atmosphere on moving to the new campus.

METHODS AND ANALYSIS

Study design

This is a prospective, observational, longitudinal whole cohort study with an A-B design, measuring service metrics and patient outcomes before and after the hospital redevelopment. The study will record baseline and subsequent measures up to a period of 5 years after the move. This follow-up period is intended to ensure that any benefits observed are sustained over the reasonable lifetime of the model of care.

Recruitment to the study commenced in December 2019 and will continue until 5 years after the NFMHS moves to the new campus at Portrane Dublin, which is anticipated to be 2027.

Study setting

This is a multisite study set between two sites of Ireland's NFMHS, CMH Dundrum and the new hospital at Portrane. The CMH Dundrum has a bed capacity of 104, while the Portrane site will have a capacity of 170.

CMH Dundrum Dublin provides, and the new development at Portrane North Dublin will provide, care and treatment to mentally disordered offenders at high, medium and low levels of therapeutic security. It is a complete NFMHS on one site.

Participants, eligibility criteria and consent

This study includes a complete cohort of patients at the NFMHS, CMH Dundrum. All in-patients who were present in the hospital or linked to the hospital as supervised community patients (those on conditional or unconditional discharge in community residences of the NFMHS) from 1 December 2019 will be included and recruitment will continue for 5 years after the transfer of the hospital to the new site at CMH Portrane, estimated to be in 2027. All will be adults, as the NFMHS does not admit patients under 18 years of age. All data gathered will be kept on a password protected database, with access strictly limited to the research team and the computer access to the database limited to the secure server of the NFMHS.

Patients will be selected for admission as per treatment as usual in the hospital, according to a process of systematic screening in remand and sentenced prisons[31] using a validated structured professional judgement instrument (DUNDRUM-1 and DUNDRUM-2) to support decision making in a governance setting[32 33] where referrals and waiting list outcomes and times to admission are systematically recorded.[1 33 34]

Eligibility criteria, consent and bias

The Dundrum Forensic Redevelopment Evaluation Study (D-FOREST) study will include the complete cohort of patients in the NFMHS during the time period of the study. The aim of including the entire cohort admitted to the secure forensic hospital is to limit bias in the results. For measures that require direct patient interviews, consent is sought in writing from the patients at the time of interview. However, observational measures are included for the entire patient cohort, including those who lack the capacity to consent to engage in research. In any forensic mental health service, a significant proportion of patients suffer from highly treatment resistant mental illness, usually schizophrenia. While many patients move forward on their care pathways to less secure places and subsequently to community discharge, a significant number present with longer term needs. Most in-patients on higher dependency wards in a secure forensic hospital lack capacity to consent to engage in treatment[35 36] or research studies. Therefore, observational measures relating to the entire patient cohort will be used to ensure that this vulnerable and highly unwell group are not omitted from the evaluation study. To omit such a group would likely bias the results towards the effectiveness of therapy and shorter length of stay in a manner that would not be a true reflection of the patient cohort.

Treatment as usual in the hospital

In addition to pharmacotherapy, 'treatment as usual' is defined in the NFMHS model of care[37] as consisting of programmes concerning physical health, mental health, substance misuse recovery programmes, offending behaviour programmes, self-care and activities of daily living (ADLs), education occupation and creativity, and family and intimate relationship therapies. These domains are deliberately broad to permit individualisation according to need and according to individual 'best fit'.[38] It is standard practice in the NFMHS for each patient to be offered 25 hours of structured activity per

week increasing in the new hospital to include a minimum of 5 hours' core treatments in mental health, offending behaviour or substance misuse.

Criteria for discontinuing or modifying interventions and treatment

Each patient has an individual care plan that is reviewed in the light of progress every 6 months. Patients may be allowed prolonged leave, conditional discharge or absolute discharge, subject to legal processes. Psychiatric reports to decision making bodies are guided by improved risk assessments and by assessment of progress in completion of treatment programmes and forensic recovery.[27 39]

Patients admitted from prisons may be diverted via the courts to community mental health services or they may be remitted to prison when they meet the legal criteria of no longer being in need of treatment that can only be given in hospital.

Outcomes, measures and time points

The service level benefits will be assessed by collating the following measures

- Time from placement on waiting list to admission.
- Annual rates of admission per 100 000 population.
- Length of stay from admission to either long leave (more than a month of continuous leave outside the secure perimeter), or to conditional discharge or to return to prison.
- Annual discharges per 100 beds and per 100 staff.
- Violent incident reports per 100 admissions per annum, per 100 beds per annum and per 100 staff per annum.
- Restrictive practices (seclusion, restraint and forced medication) per 100 admissions per annum, per 100 beds per annum and per 100 staff per annum.

The patient-level benefits will be assessed using a combination of baseline measures and repeated measures, and using a combination of patient and interview rated measures and observer or clinician rated measures (table 1).

Observational measures and interview measures of risk, recovery and functioning will be rated for the group

The measures will be rated at three distinct overarching time points on a patients' recovery journey through the secure forensic service. These time points include the first the preadmission time point battery, second early admission measures will be taken in the first 3 months of admission and thirdly measures of longer term recovery, which will be rated once every 6 months for the duration of the patient's care and treatment in the NFMHS (figure 1).

Preadmission measures, measures taken when a patient is accepted onto the NFMHS waiting list, and admission agreed as being clinically necessary

DUNDRUM-1 triage security scale and DUNDRUM-2 triage urgency scale

The preadmission measures of D-FOREST study will include structured assessments of need for therapeutic security and urgency of need for admission, using the DUNDRUM-1 and DUNDRUM-2 instruments.[40] These will be measured at the point where a patient is accepted onto the hospital waiting list, by the NFMHS admission panel. DUNDRUM-1 triage security rates a patient's level of need for therapeutic security, it supports clinician decision-making when deciding whether a patient requires admission to a high, medium or low secure forensic hospital setting.[40] It is a structured professional judgement instrument and has been internationally validated and has strong psychometric properties.[1 32 34] The DUNDRUM-2 triage urgency scale is designed to triage the urgency of need for admission for patients on a forensic hospital waiting list and supports clinicians in prioritising the most urgent cases on a forensic waiting list.[33 40]

Early-admission measures, measures taken during the first three months of admission

The starting point for evaluation of the effect and benefit from treatment must be an accurate assessment of demographic characteristics, offending history and baseline pathology including physical and mental health.

In a secure forensic hospital relevant baseline measures include both mental illness and personality disorders, as well as physical health (medical) illnesses. Measures of physical health will be taken at the time of admission, including BMI, Fried's Frailty Measures, sedentary behaviour measures (SIT-Q) and other routine physical health measures as part of a routine primary care (General Practitioner led) assessment for all new in-patients. An Assessment of Motor and Process Skills and assessment of functioning (Mental Illness Research, Education and Clinical Center version of Gobal Assessment of Functioning (MIRECC GAF)) will also be completed.

Within the first month of admission, all patients will have a Structured Clinical Interview for DSM-V assessment to assess mental health diagnostic criteria, Positive and Negative Symptom Scale (PANSS) to assess the positive and negative symptoms of schizophrenia. Personality disorder will be assessed using the MMPI-2 initially and if there are elevations in personality scales an International Personality Disorder Examination will then be administered.[41] A Psychopathy Checklist Screening Version to assess for the presence of co-morbid psychopathic traits will also be completed for each patient on admission.[42]

A battery of neurocognitive measures will be administered to each newly admitted patient as follows. Matrics Consensus Cognitive Battery (MCCB) is a brief assessment of cognitive domains relevant to schizophrenia. The Delis-Kaplan Executive Function System is a cognitive test used to assess deficits in the frontal lobe and higher level executive functioning.[43]

Medium to longer term measures, measures of treatment outcomes and recovery taken once every 6 months during the entire duration of the admission

Symptomatic recovery and physical health measures

Physical health and functioning

Physical health measures such as BMI will be taken on a 6 monthly basis, as part of the routine outcomes from primary care monitoring for the patient group. Measures

Table 1 Primary outcome measures

	Preadmission measures	Baseline measures taken at admission	Measures taken 3 months after admission	Measures taken on a 6-monthly basis during the course of the admission	Measures taken on discharge
Service related measures					
	Admissions/100 000 PY	Seclusion on admission	Violence/100 adm PY	Violence/100 beds PY	Discharges/100 beds PY
			Restrictive practices/100 adm PY	Restrictive practices/100 beds PY	Discharges/100 staff PY
	Time on waiting list	Previous admissions	Time to move to less secure place	Time to first leave	Time to conditional discharge
Individual patient related measures					
Static measures.	DUNDRUM-1	SCID	SIMS		
		IPDE	PCL-SV		
		MCCB	D-KEFS		
			AMPS		
Functional and physical health measures		MIRECC GAF	MIRECC GAF	MIRECC GAF	MIRECC GAF
		Frailty and SIT-Q	Frailty and SIT-Q	Frailty and SIT-Q	Frailty and SIT-Q
Personal recovery measures		WHO-QOL	WHO-QOL	WHO-QOL	WHO-QOL
		EssenCES	EssenCES	EssenCES	EssenCES
Forensic recovery measures		HCR-dynamic	HCR-dynamic	HCR-dynamic	HCR-dynamic
		SAPROF	SAPROF	SAPROF	SAPROF
		S-RAMM	S-RAMM	S-RAMM	S-RAMM
		DASA	DASA		
		DRILL	DRILL		
		DUNDRUM-3	DUNDRUM-3	DUNDRUM-3	DUNDRUM-3
		DUNDRUM-4	DUNDRUM-4	DUNDRUM-4	DUNDRUM-4
		Concordance	Concordance	Concordance	Concordance

Measures are change from baseline unless indicated otherwise.
AMPS, Assessment of Motor and Process Skills; DASA, Dynamic Appraisal of Situational Aggression; D-KEFS, Delis-Kaplan Executive Function System; DRILL, DUNDRUM Restrictions and Intrusions on Liberty Ladders; HCR, Historical Clinical and Risk; IPDE, International Personality Disorder Examination; MCCB, Matrix Consensus Cognitive Battery; MIRECC GAF, Mental Illness Research, Education and Clinical Center version of Global Assessment of Functioning; PCL-SV, Psychopathy Checklist Screening Version; SAPROF, Structured Assessment of Protective Factors for violence risk; SCID, Structured Clinical Interview for DSM-V; S-RAMM, Suicide Risk Assessment and Management Manual; WHO QOL, WHO Quality of Life.

of self-rated sedentary behaviours will be measured on a 6 monthly basis using the adapted SIT-Q tool.[44] Global Assessment of Function will be assessed using the DSM IV standard measure (GAF MIRECC).[45]

Symptoms of major mental illness

The PANSS scale will be used once every 6 months to measure progress towards remission from psychotic symptoms, including positive, negative and general symptomatology measures.

Risk of suicide or deliberate self-harm

The Suicide Risk Assessment and Management Manual is a structured professional judgement instrument designed to guide clinicians management of risk of deliberate self-harm.[46–48]

Forensic recovery: measures of recovery from offending behaviours

Historical, Clinical and Risk for Violence-20

The Historical Clinical and Risk for Violence-20 (HCR-20)[49 50] will be used to measure risk of harm to others and is one of the most widely used measures in secure forensic psychiatric hospitals internationally. It was the first structured professional judgement instrument and went on to influence a generation of instruments to rate violence and other outcomes in secure services, including the

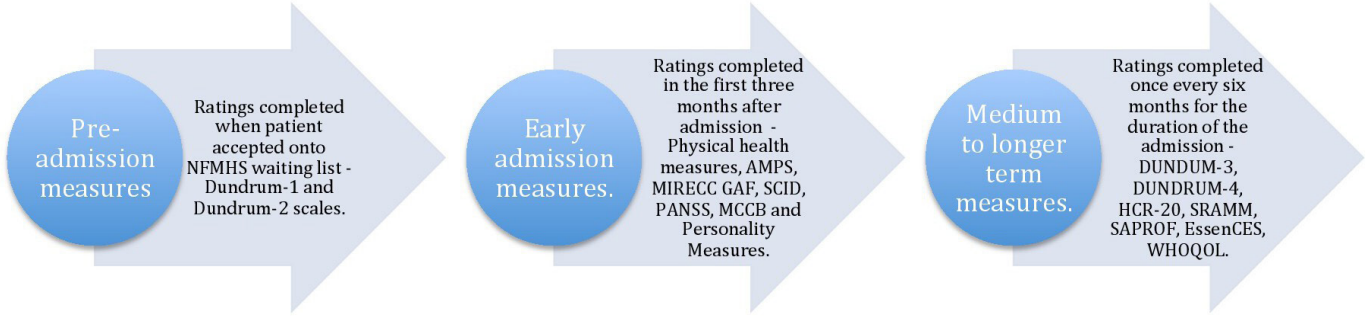

Figure 1 DUNDRUM-1 Triage Security Scale. DUNDRUM-2 Triage Urgency Scale. Assessment of Protective factors against violence. AMPS, Assessment of Motor and Processing skills; GAF, Global Assessment of Functioning; HCR-20, Historical, Clinical and Risk for Violence-20; MCCB, Matrics Consensus Cognitive Battery; NFMHS, National Forensic Mental Health Service; PANSS, Positive and Negative Syndrome Scale; SARMM, Suicide Risk Assessment and Management Manual; SCID, Structured Clinical Interview for DSM; WHO QOL, WHO Quality of Life scale.

DUNDRUM-toolkit.[40] The HCR-20 has excellent psychometric properties and is considered the standard for most international forensic hospital settings.

SAPROF

The Structured Assessment of Protective Factors for violence risk (SAPROF) is a structured professional judgement instrument designed to assess protective factors against violence.[51] It is designed to be complementary to the violence risk assessments completed with other SPJ instruments, usually HCR-20. It is a strengths based approach, offering a novel approach to violence risk management for patients in secure forensic services. It has been internationally validated[45] and has good psychometric properties.

Dynamic Appraisal of Situational Aggression

The Dynamic Appraisal of Situational Aggression (DASA) scale is a short-term risk of violence assessment instrument. It rates the patient's risk of violence on that day in question against their own baseline, and has been shown to have excellent psychometric properties. The DASA tool will be rated for every in-patient once daily on acute wards.

Restrictive practices

Rates of restrictive practices including numbers of seclusion episodes, hours in seclusion and any use of approved restraint techniques as part of the management of significant violence and aggression will also be monitored. Restrictive practices are defined in law and recorded in accordance with requirements of mental health legislation in Ireland. Restrictive practices are also defined and measures set out in the DUNDRUM Restrictions and Intrusions on Liberty Ladders, which has been validated as a means of testing proportionality in the use of these interventions to prevent imminent violence.[52]

Functional recovery: measures of therapeutic programme completion and recovery of functioning

Functional recovery in secure forensic mental health settings is about increasing independence, and developing life skills on a graded basis, to promote a return to the community setting with as much independence as possible for all patients. Measures of therapeutic programme completion such as the DUNDRUM-3 Programme Completion scale are designed to include measures of programme completion in the areas of ADLs, social and occupational functioning to assess unmet need in this area. The DUNDRUM-4 Forensic Recovery scale assesses recovery in a broad sense, underlining the importance that recovery in forensic settings is more than just recovery from active symptoms of psychosis and indeed can be independent of recovery from active symptoms of psychosis.

Personal recovery: measures of quality of life and personal aspects of recovery

Personal recovery within secure forensic services is defined by the patient's own view of their recovery of their own agency, hope and their own satisfaction with quality of life (QOL) and their living environment. Measures including the EssenCES ward atmosphere scale[53] and WHO QOL[54] will be offered to all in-patients to complete on a 6 monthly basis. Concordance between treating clinician and patient is a significant predictor of progress in forensic psychiatry and is measured by the difference in clinical rated and patient self-rated scores on DUNDRUM-3 treatment programme completion and DUNDRUM-4 forensic recovery.[39]

The HCR-20, SRAMM, DASA, DUNDRUM-1, DUNDRUM-3 and DUNDRUM-4 are routinely measured as part of routine clinical care outcomes in the NFMHS and will be collated by the research team. The additional measures will be rated by the researchers for the D-FOREST study.

Patient and public involvement

The research question was developed in response to multiple critiques of the age of the building and physical infrastructure at the 19th century building of Dundrum hospital the current site of the NFMHS. This included critiques from international review groups such as the

Committee for Prevention of Torture, Inhuman and Degrading treatment (Council of Europe), Quality Network for Forensic Secure Services, Royal College of Psychiatrists, and from the Mental Health Commission (Ireland) and from family and patient advocacy groups. The research question is designed to evaluate the patient benefit from the move to the new hospital campus at Portrane, North Dublin. When planning the redevelopment of the NFMHS, priorities identified by patients and family members, were carefully considered and included as key outcome measures for this study, including length of time on the waiting list for admission, length of stay and access to therapies. A further key outcome measure of the study is the self-rated Dundrum programme completion and recovery scale. This was developed in conjunction with a patient researcher and this patient has been included as a published author in the initial validation study for this instrument. Patients are not directly involved in the recruitment to the study. The progress of the study will be disseminated to all patients in the service using the NFMHS patient newsletter which is regularly published. The results of the study will also be disseminated to the participants and all patients in the service using the hospital patient forum and via the NFMHS patient newsletters.

STATISTICAL ANALYSIS PLAN

All statistics will be calculated using SPSS version 27 or equivalent.

Data management and oversight

The principal investigator (MD) will take responsibility for the conduct of D-FOREST. Site investigators will supervise the day to day operation of the project and are responsible for ensuring that Good Clinical Practice guidelines for research are followed.

The principal investigator (MD) of the D-FOREST research team will monitor the data. The principal investigator will review the data on a regular basis and a random sample of 10% of completed data measures thereafter. Monitoring will ensure protocol compliance, proper study management and timely completion of study procedures.

Data storage and security

Data will be stored on password-protected computers behind institutional firewalls only. Hard copy records will be stored in locked cabinets within the secure forensic hospital setting, a secure site in and of itself. Access to data will be strictly limited to study personnel. Study data will be anonymised and a master linking log kept separately. All results presented and published will consist of anonymised aggregated findings only.

Sample size

As this is a whole cohort prospective observational study, a 'sample' size cannot be calculated. It is more relevant to estimate the proportion of data that is not provided so that possible bias can be sought through comparison of measured and unmeasured patients. This national cohort has been extensively studied and reported so that likely effect sizes and time scales are known.[6 55–58] A calculation of the possibility of type 1 error and type 2 error will be provided in all analyses, with post hoc corrections for multiple hypothesis testing where relevant. Appropriate tests and corrections will be employed for paired observations and repeated measures.

Statistical assumptions concerning this cohort and samples of this cohort have been described recently.[57 59]

Starting with between 84 and 94 male and 10 female patients in the 1850s hospital, this will increase to 110 male beds and 20 female beds in the new hospital with a further 30 beds in the following year. Admissions for male patients will increase from 20 to 30 per annum to 60 per annum while admissions of female patients will increase from 10 per annum to 20 per annum. Factors affecting length of stay in this population have been described elsewhere.[5]

Type 1 and type 2 errors can be assessed from known effect sizes in this population. In a prospective observational study in CMH Dundrum a cohort of patients with schizophrenia followed over 4 years,[6] 123 patients were eligible at baseline and full data were available at 4 years for 69. Change in DUNDRUM-3 was significant p=0.004, Cohen's d=0.367, Reliable Change Index[60] for mean DUNDRUM-3 was 0.81 or less than one whole unit (RCI) achieved in 37% of patients, and reliable and meaningful change (RMC) of one whole unit or more was achieved in 23% of patients. For the HCR-20 measure of violence proneness, the HCR-20-C scale (current, clinical risk) changed significantly over 4 years Cohen's d=0.377, p=0.003 with Reliable Change Index calculated as 3.35 units, achieved in 10% of patients. Since 3.35 cannot be related to any meaningful change or outcome, RMC could not be calculated. In another study in this population, a randomised controlled trial of cognitive remediation therapy in patients with schizophrenia in CMH Dundrum, 65 patients were randomised and 50 completed the study. Comparing active treatment with treatment as usual, change in the MCCB was significant with effect size Cohen's d=0.34, p=0.03.[58]

Statistical methods for primary and secondary outcomes

Time intervals (time in days to admission from waiting list, length of stay) will be measured by median and 95% CI using Kaplan-Meier and Cox regression analyses. Survival analysis will be used to assess factors affecting length of stay.[5 61]

Patient-level measures will be expressed as changes from baseline (typically from the time of admission) using ANCOVA, MANOVA or logistic regression as appropriate with correction for the effects of static baseline variables such as demographic characteristics (eg, age, sex and ethnicity) or diagnosis including multiaxial diagnoses, neurocognitive function and legal status.

Repeated measures will be analysed for effects on outcomes and covariates using general estimating equations as recently described in similar populations[62] and in this population.[52] Measures of effect size will be used alongside measures of statistical significance for primary and secondary outcomes. At the individual-level measures of reliable and clinically meaningful change will be calculated and proportions achieving this will be expressed with 95% CIs.[60]

Analysis of repeated measures using generalised estimating equations will be used to compare mean scores on measures of physical health, risk of violence, therapeutic programme completion, recovery and overall functioning, at time points in advance of the move of the NFMHS to the new Portrane Campus and for 5 years after the move.

Mediation analysis will be used to elucidate causal models for mediating and moderating factors when testing relationships between measured changes, outcomes and baseline characteristics. Hayes PROCESS macro model[63 64] has been used for such analyses in other studies in this population.[6 56 58]

Lagged causal model analysis will be used to assess the existence and significance of potential directed relationships between the baseline measures of symptomatology of schizophrenia and violence risk and final outcome namely length of stay.[65] The lagged causal model approach will be used also to examine the relationship between amount of 'treatment' received and change in outcome measures. 'Treatment' here may at its most simplistic be related to length of stay. At the next level, it can be related to numbers of relevant staff employed and in post.[66] At a more significant level, it can be related to hours of face to face contact with trained therapists, the 'input' in the 'logic model'.[37]

Interim analyses

Interim analyses will be carried out in the order described in figure 1, with preadmission and baseline measures available first, then early measures of change followed by medium and longer-term measures of change.

Additional or subgroup outcomes

Outcome measures for women, older patients[67] for patients with intellectual or developmental disorders, for those with or without personality disorder and for those admitted to an acute low secure unit will be reported and will be contrasted with other groups.

Data management and oversight

The principal investigator (MD) will take responsibility for the conduct of D-FOREST. Site investigators will supervise the day to day operation of the project and are responsible for ensuring that Good Clinical Practice guidelines for research are followed.

The principal investigator (MD) of the D-FOREST research team will monitor the data. The principal investigator will review the data on a regular basis and a random sample of 10% of completed data measures thereafter. Monitoring will ensure protocol compliance, proper study management and timely completion of study procedures.

Data storage and security

Data will be stored on password-protected computers behind institutional firewalls only. Hard copy records will be stored in locked cabinets within the secure forensic hospital setting, a secure site in and of itself. Access to data will be strictly limited to study personnel. Study data will be anonymised and a master linking log kept separately. All results presented and published will consist of anonymised aggregated findings only.

ETHICS AND DISSEMINATION

This research project has been approved by the Research, Ethics and Effectiveness Committee of the National Forensic Mental Health Service, approval number AUD/140220/MD. Ethics approval was based on the above methodology. The authors assert the methodology of this study is compliant with the Declaration of Helsinki.

It is planned that the results of this study will form the basis for peer-reviewed papers to be submitted to international journals and form the basis for presentations at international forensic mental health conferences.

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Contributors MD designed the study, in conjunction with HGK. MD and HGK designed the statistical approach with contribution from KO'R. All contributed to the authorship of the protocol.

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