IRAS ID: 265168

Enhancing de-escalation techniques in adult acute and forensic units: Development and evaluation of an evidence-based training intervention. (EDITION)

PROTOCOL

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V3 2/8/2019

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1) RESEARCH TEAM & KEY CONTACTS

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2) INTRODUCTION

This protocol outlines plans to deliver and evaluate the feasibility, acceptability and potential impact of an evidence-based, de-escalation training package as part of a wider NIHR program of research called EDITION (Enhancing de-escalation techniques in adult forensic units: Development and evaluation of an evidence-based training intervention).

Our aim is to develop and evaluate a feasible, acceptable, evidence-based de-escalation staff training program to reduce rates of conflict and restrictive practices in adult acute and forensic inpatient mental health settings. Although training in de-escalation techniques is provided for NHS staff, no training is proven by research to be effective. Additionally, research shows practices such as restraint are used more often than they should be. Developing and evaluating new training is therefore urgently needed in this area.

The program consists of three work packages:

> **Work Package 1- Updating evidence**: This will involve updating two published reviews in the area and conducting two original qualitative studies to explore experiences of de-escalation techniques and training in both forensic and acute/psychiatric intensive care units.
>
> **Work Package 2-Developing intervention**: The Behaviour Change Wheel and COM-B model will be used to develop an intervention. Evidence from WP1 will be synthesised to develop a new training package within the research team.
>
> **Work Package 3-Assess feasibility of intervention:** The training package will be evaluated in a mixed-method, uncontrolled, case-study in 10 wards across 2 sites. This will include a range of adult acute and PICUs, and forensic high, medium and low secure units.

Ethical approval is being sought here for delivery and evaluation of the training package for WP3. All relevant information is included in the IRAS form and accompanying documents. Ethical approval has already been gained for WP1 (IRAS ID: 235692 and REC ID 18/YH/0035 - 235692) and was not required for the other components of WP2, which involved updating systematic reviews from existing research and work within the study team.

3) BACKGROUND

The term ‘conflict’ refers to patient behaviours that compromise safety in in-patient mental health settings e.g. aggression, self-harm and suicide, rule-breaking, drug (illicit or un-prescribed) and alcohol misuse, medication refusal . The term ‘containment’ refers to interventions used by inpatient staff to reduce conflict-related harm by restricting patient autonomy, e.g. PRN and Rapid Tranquilisation (RT), seclusion, enhanced observations and manual restraint (Bowers 2014). Conflict and containment are prejudicial to both staff and patient safety and wellbeing (Appleby et al. 2006;Itzhaki et al. 2015;Paterson et al. 2003;Renwick et al. 2016;Steinert et al. 2013) and account for approximately half of the total expenditure of inpatient mental health services (Flood et al. 2008;Hallett and Dickens 2017). Interventions that can safely reduce conflict behaviours without containment are highly sought after.

‘De-escalation’ refers to verbal and non-verbal skills and strategies used by staff to reduce emerging conflict behaviours without containment (NICE 2015). Despite being a core intervention to reducing conflict and containment (NHS 2004;NHS 2005), there is no evidence-based model on which to base training (Price et al. 2015). The capacity of current training to impact on practice may be limited by a lack of evidence-informed content sufficiently tailored to the needs of diverse care settings and patient subgroups in mental health services (Department of Health 2014). Developing an evidence-based, context sensitive de-escalation techniques training package may have substantial benefits to the safety and clinical and cost-effectiveness of mental health services. Given that de-escalation techniques are a component of mandatory training for all NHS staff (NHS 2004), these potential benefits may extend beyond mental health services.

This project is funded by the National Institute of Health Research Health Technology Assessment.

4) STUDY OBJECTIVES

4.1 Aim

To develop and evaluate an evidence-based training package to enhance the implementation and effectiveness of de-escalation techniques in practice.

4.2 Objectives

1. Confirm the key components and mechanisms of effective de-escalation and explore variations across different service settings.

2. Derive and validate a conceptual map explaining effective de-escalation in practice, accounting for differences in service user and staff characteristics and organisational contexts.

3. Develop with stakeholders an effective, acceptable and context-sensitive de-escalation training package for mental health staff.

4. Evaluate training package effects on use and effectiveness of de-escalation and rates of restrictive practices.

5. Explore the processes underpinning training implementation and impact and understand the individual and organisational factors inhibiting or enabling routine use.

6. Disseminate learning through effective knowledge mobilisation.

5) STUDY DESIGN & PROTOCOL

This protocol describes the methods for evaluating the training package in a mixed-method, uncontrolled, case-study in 10 wards across 2 sites. This will include a range of adult acute and PICUs, and forensic high, medium and low secure units.

WP3: Case Study Evaluation

Aim:

To deliver and evaluate the feasibility and acceptability and potential impact of our evidence-based, de-escalation training package and supplementary implementation guidance.

Objectives:

1. Establish the feasibility of embedding our intervention into secondary care mental health services by monitoring training uptake and engagement rates, and exploring, from multiple stakeholder perspectives, potential barriers and enablers to its implementation.
2. Establish the feasibility of conducting a randomised controlled trial to determine the clinical and cost-effectiveness of our intervention, by quantifying participant recruitment and retention, and identifying the optimal strategies to overcome any difficulties experienced.
3. Examine the applicability (content validity) and acceptability (full and partial completion rates, sensitivity-to-change) of proposed trial outcome measures and the need for additional, patient-prioritised outcomes.
4. Collect outcome data to help inform the parameters of a fully-powered trial, including identification and standard deviation of the proposed primary outcome measure for sample size.

Design:

Mixed-method, uncontrolled, case study evaluation. An uncontrolled design permits the inclusion of a diverse range of clinical settings and an in-depth examination of contextual variation in training effects. In line with commissioning brief requirements, the proposed study will determine the feasibility of our training intervention and the feasibility of progressing to a full RCT. It will add to existing evidence underpinning training implementation and impact in a pragmatic clinical setting.

Method:

Target population: Staff and in-patients in adult acute and forensic settings. Feasibility trial participants will be different to those participating in Phase 1 and 2 intervention development. All participants will have capacity to consent (checked by the nurse-in-charge prior to any researcher contact) and be able to read and write in English to engage with study materials. Translation of outcome measures will be prioritised in a future study should our intervention show promise.

Sample: Our case study design permits an in-depth examination of contextual variation in training effects, enhanced through the inclusion of a diverse range of clinical settings. It will not formally test the effects of the intervention and a formal power calculation is not appropriate. Instead, training will be delivered and evaluated in a purposive sample of 10 wards (encompassing male and female acute, PICU, low, medium and high secure wards), recruited from four different research sites. Both sites have agreed to participate in this study and our research team includes clinical site leads as named collaborators (Doyle, Kidder, Murray, Turner, Noak).

Intervention: A dedicated de-escalation techniques training package (EDITION) will be delivered for all ward staff in each of the ten wards to supplement existing NHS PMVA training. We will train approximately 30 staff per ward. Our clinical site partners have indicated that attendance at training will be mandatory. Intervention content will be co-developed with multiple stakeholders, including service users, carers and health professionals in Phases 1 and 2. Session content will be informed by our Phase 1 research and our Phase 2 synthesis. Training will be collaboratively delivered by Professor Patrick Callaghan (training lead), PMVA training staff at the two participating Mental Health Trusts and service user (Grundy) and carer (Cree) co-applicants. The PMVA leads for

Broadmoor Hospital and South West Yorkshire Partnership NHS Trust) are named collaborators on our bid. The intervention package is outlined in a separate document (EDITION Intervention Protocol.)

Outcomes: Data will be collected at 8 weeks pre-and 8 weeks post-implementation (with an intervening 8 week implementation period).

Feasibility outcomes: The primary outcomes for this study are feasibility outcomes. We will quantitatively assess recruitment and retention rates, intervention uptake and engagement rates, full and partial completion rates for our proposed outcome Ps and variability and potential floor and ceiling effects in these outcomes. We will monitor AEs and report these at regular intervals to our steering committee. SAEs will be reported to the CI, REC, funder and the sponsor within 15 days (see EDITION Adverse Events Protocol, included separately.)

Training outcomes: We will assess de-escalation performance immediately pre-and-post-training. Each consenting participant will be video-recorded pre-and-post training completing a standardised role play. Each recording will be coded by researchers to identify whether it was recorded pre or post-training. Recordings will be sent to independent external raters who will be blinded to pre-or-post-training designation and who will rate performance using the De-escalating Aggressive Behaviour Scale (EM-DABS), a validated observer-rated measure of de-escalation performance. Training acceptability will be assessed via the Training Acceptability Rating Scale (TARS) which measures knowledge, confidence, applicability, quality and satisfaction of training. The TARS will be completed by all consenting participants at a single time-point immediately post-training.

Clinical outcomes: Clinical outcomes will use both staff and patient reported measures. The PCC-SR, a validated measure of conflict and containment rates, will be completed by the nurse-in-charge at the end of every shift. The PCC-SR will be completed for each the 10 participating wards, throughout the full 24 weeks of data collection (8 weeks pre-training implementation, 8 weeks implementation and 8 weeks post-training implementation). Three additional staff-reported outcomes (COM-B behaviour change model, attitudes to containment scale, and attitudes to personality disorder questionnaire will be collected at four time-points: Week 1 and 8 of the pre-implementation and Week 16 and 24 of the post-implementation data collection period. Three patient-reported clinical outcomes (Perceived

expressed emotion in staff scale; Coercion Experience Scale and the Violence Prevention Climate Scale will be collected at 7 time-points: Weeks, 1, 4 and 8 in the pre-implementation phase; week 12 in the embedding phase; weeks 16, 20 and 24 in the post-implementation phase.

Case note review:

Because the PCC-SR is a shift-report, missing data can be a problem. We will supplement this by using patient case-notes (where these are made available by the ward), which will be coded quantitatively according to the categories of the PCC-SR. No non-anonymised patient data will leave the sites, and the case-notes will be coded either by a researcher (following removal of any identifiable information), or by a member of clinical staff who is part of the direct-care team on the ward. There is a possibility that personal information will remain in the body of the case-note (the clinical staff will not read through each case-note but will search for name, date of birth and NHS number and redact these), if this occurs it will be raised immediately with the chief investigator.

Economic outcomes:

- Staff and patient reported health status: EQ-5D-5L (17)
- Service use associated with the current and new training package has already been collected from focus groups, will be collected from structured surveys from staff (to be developed and submitted as an amendment for ethical review.)

Process Evaluation: We will conduct a process evaluation, across our 10 wards to explore the contextual feasibility and acceptability of our interventions and the potential mechanisms by which intervention components interact with context to produce intended and unintended outcomes (i.e. what seems to work, for whom, under what circumstance). Our process evaluation will adopt an ethnographic approach, relevant for studying the implementation of complex interventions. Structured observational methods will be used to focus on professional and service user interaction with the intervention. Participant observation will be conducted by researchers who will be trained and supervised by experienced qualitative researchers (Bee, Brooks). Each of the ten wards will be observed (once informed consent from all relevant parties is obtained) for 15 hours (over 2 days) in the eight week pre-implementation phase and 15 hours (over 2 days) in the post-implementation phase, a project total of 300 hours observation across ten wards.

Observations will be guided by a schedule consistent with the training content (which is still in development) and detailed notes will be taken.

Participants involved in the observations will take part in post-observation semi-structured interviews to explore emergent themes from the observations in more depth. The number and characteristics of interview participants will depend on the situations that emerge during observation but, where required to achieve sufficient sample diversity, we will interview additional patients and staff that have not been observed. Because of the diversity of settings included in our project we anticipate a minimum of 30 staff and 30 patient interviews will be required to reach data saturation. 5-10 semi-structured interviews with service managers will be conducted separately from the observations. All interviews will be digitally recorded and transcribed verbatim.

Analysis:

***Quantitative outcomes*:** In keeping with the aims of our feasibility design, our data analysis will be mostly descriptive. We will quantify intervention uptake and engagement rates, and use simple descriptive statistics, including full and partial completion rates, frequency distributions and measures of central tendency and dispersion, to assess the completeness and variability of participant and cost outcome measures collected at each data collection point. Costs will be calculated from the NHS perspective. Secondary analysis will include costs from the patient perspective and approximate a societal perspective. We will undertake exploratory comparisons of intervention outcomes recognising that these analyses will be underpowered.

***Qualitative data*:** Analysis of interview and observational data will be conducted according to the constant comparative method whereby analysis will be carried out concurrently with data collection so that emerging issues can be explored iteratively. Pseudonymised verbatim transcripts of audio recordings and typed observation notes will be imported into the software package NVIVO for data management and analysis. Analysis will use Framework methodology , facilitating a combination of inductive and deductive coding. Codes that emerge from the data will be compared with important codes identified in earlier phases of the project. The project team will meet regularly to develop the coding framework, to discuss alternative interpretations and ensure the coding framework remains

grounded in the data. To ensure analytical rigour, the resultant framework will be presented to the wider project team and project steering group for discussion and comment..

6) STUDY PARTICIPANTS

6.1 Inclusion Criteria:

- English speaking (owing to lack of resources to fund interpreters)

- **Service users**

  - Current inpatient within an adult (18+) acute, psychiatric intensive care unit or adult forensic unit (low, medium or secure)

  - Able to provide informed consent

- **Clinical staff**

  - Ward-based clinical staff working in acute, PICU and forensic adult mental health services (nurses, support workers, nursing assistants)

  - Minimum of 6 months experience (considered enough time to have had sufficient experience to be able to contribute to the aims of the research)

- **Non-ward based staff** currently working in acute, PICU and forensic adult mental health services (service managers, occupational therapists, clinical psychologists, psychiatrists, registered nurses and service managers)

  - Minimum of six months experience

6.2 Exclusion Criteria:

- Non-English speaking

- Clerical, domestic and other non-clinical staff

- **Service users**

- Not a current inpatient of adult forensic/acute/PICU mental health services

- Lack of capacity as judged by the researcher or the nurse-in-charge on the ward

- **Clinical Staff**

- Less than 6 months clinical experience

6.3 Recruitment:

Ethically approved flyers will be placed in patient and staff areas, which will include the chief investigators contact details to enable potential participants to ask questions about the study.

The Nurse-in-charge will assess the capacity of service users prior to engagement with the study. A trained researcher will be obtaining written informed consent from all participants in the study.

The nurse-in-charge will approach staff-members and inform them about the study using the materials provided, asking them to fill out and return a consent-to-contact form if they are willing to be contacted by a researcher.

Following participation in the training, the researcher present will ask staff members if they are willing to complete post-training measures.

The nurse-in-charge will approach patients and inform them about the study using the materials provided, gaining verbal consent for the researcher to contact them subsequently. Prior to written consent being given, the nurse-in-charge will only identify the potential patient participants using their initials to researchers. Patients will also have the option of returning consent to contact forms to researchers.

Service users

During the first contact the CI (or trained researcher) will confirm the service user's understanding of the project, answer any questions, check eligibility in an informal way (using a checklist of the exclusion and inclusion criteria), and advise the service user to spend a minimum of 24 hours deciding whether they still wish to participate. A further meeting will be arranged to conduct the interview or complete the questionnaire measures. If during the period between first contact and the interview the service user decides they no longer wish to participate, they will be advised to inform the NIC who will inform the CI. Formal consent will be taken on the day of the interview.

Staff

On first contact with the member of clinical or training staff (by phone or email depending on preference indicated on the CTC) the PI will check eligibility (using a checklist of the exclusion and inclusion criteria), advise them to spend a minimum of 24 hours deciding if they still wish to participate and arrange a further meeting to complete the interview or questionnaire measures. If, during the intervening period between first contact and the interview the staff member decided they no longer wish to participate, they will be advised to inform the CI (from the details on the leaflet). Formal consent will be taken at the research interview.

6.4 Participants who withdraw consent or lose capacity to consent:

Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected. At each stage of recruitment it will be clearly stated to all participants that participation in the project is voluntary and that their consent can be withdrawn at any time and data destroyed upon request.

Participants will complete measures at a particular time point, with some patient participants only completing a set of measures at one-time point (if they lose capacity to consent, are discharged from the ward or move wards. In any of these cases their data will be retained.)

Given the context of the intervention, there is a strong possibility that some patients will lose capacity to consent, particularly on admission and PICU wards (where there is expected to be a higher level of

fluctuation in terms of capacity.) The clinical team will be responsible for monitoring capacity to continue in the study, and will inform the research team if there are any concerns about capacity.

7) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

All interviews will be digitally-recorded (with consent) and transcribed verbatim. Arrangement for data storage and retention will adhere to the Data Protection Act (2018). All data will be stored for ten years following the end of the study. Paper records will be held in secure storage at the University of Manchester and the University of Surrey for the duration of the study, and archived at the University of Manchester. Personal identifiable data will be stored separately from pseudonymised data. All electronic data will be held on password protected servers at the University of Manchester or the University of Surrey, and archived at the University of Manchester. Service users will be informed that anything discussed will be kept confidential unless they divulge information that suggests risk to themselves or others. In those instances confidentiality would need to be broken and the nurse in charge informed. Staff members who participate will be informed their confidentiality will only be broken if evidence of practice harmful to service users emerges during the interview. This would be reported in line with the code of professional conduct.

8) ETHICAL CONSIDERATIONS

The main risk issues this study raises are: risk of participant distress during interviews and risk of increase in rates of conflict and containment as a result of the intervention.

Distress

The qualitative work is likely to cover potentially distressing experiences such as violence and experience of restrictive practices. There is evidence that these experiences can induce symptoms of post-traumatic stress in both service users and clinical staff. To manage this risk, the interviews will be conducted in a supportive manner. A distress policy will be developed which will be adhered to at all times. Participants will be encouraged to let the interviewer know if the interview is causing

distress and they would like to stop or take a break. They will be made aware that they can withdraw consent at any time including after the interviews have taken place and their data can be destroyed upon request.

Increase in rates of conflict and containment

There is a potential that rates of conflict and containment will increase as a result of the training intervention. This is particularly significant given due to the design of the study, patients will not consent to receive the intervention (as all staff in participating wards will receive EDITION training.) This will be monitored through the adverse events protocol (see EDITION Adverse events protocol.)

9) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

10) FUNDING

This study has been funded by the National Institute of Health Research, Health Technology Assessment (16/101/02).

11) PUBLICATION POLICY

Results of our studies will be published in open-access, high impact factor journals. We will provide all participants with a report of the findings.

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