Critical Time Intervention for Severely Mentally Ill Released Prisoners: A Randomised Control Trial (CrISP)

Background

The risk of suicide and relapse increases substantially when people with mental illness move between institutions and the community[1-4]. Mentally ill prisoners receive little preparation for resettlement into the community[5]. In a recent study we found that continuity of care upon release was profoundly unsatisfactory for men with severe and enduring mental illness (SMI); of 200 clients receiving care from prison in-reach services, only three went on to make contact with community services after discharge[6]. It is widely accepted that discharge planning remains a major weakness in services for mentally ill offenders[7], but at present we know little about the best service models for promoting continuity of care for this group.

Case management was established two decades ago as a service modality through which to co-ordinate and integrate mental health and social care within limited resources[8] and became a cornerstone of UK community mental healthcare[9]. Evidence of the efficacy of case management is mixed; it has been shown to increase the likelihood of engagement with psychiatric services but also to increase the number of hospital admissions, show no overall improvement to health and social outcomes and be more costly than standard care[10]. Other recent studies have demonstrated the benefits of case management[11-14], including in forensic populations[15], particularly when combined with social and housing support[16].

Assertive Community Treatment (ACT), a variant of case management, is an established, effective model for promoting engagement in people with mental illness[17]. The ACT model is one of the most extensively evaluated mental health interventions and there is good evidence for its efficacy[18,19].

Critical Time Intervention (CTI) is an adaptation of ACT emphasising time-limited, intensive case management at times of transition. The purpose of CTI is to establish a stable support network in the community, forging enduring links with local mental health services for people especially vulnerable through a lack of established community ties; for example those who are homeless or who have limited/no close family support. CTI has been proved to be effective in promoting engagement in homeless people with mental health problems released from hospital[20,21]. Susser et al[20] looked at all men discharged from an on-site psychiatric programme at a men's shelter in New York between 1991 and 1993. Ninety-six men took part, all with severe mental illness. Participants were randomly assigned to receive usual services only (USO) or CTI. CTI was applied for nine months, after which the group then returned to USO for the remaining nine months of the study. The average number of homeless nights over the 18 month study was 30 for the CTI group and 91 for USO. During

the last month of follow-up, four (8%) of the CTI and 11 (23%) of the USO group were homeless. Extended homelessness (more than 54 nights) occurred in 10 (21%) of the CTI and 19 (40%) of the USO group. Following the nine months CTI period, differences between the groups did not diminish. The authors concluded that CTI significantly reduced homelessness in comparison to USO.

Mentally ill prisoners have much in common with homeless mentally ill people, in terms of the problems their often chaotic lifestyles present when attempting successful resettlement into the community upon release from custody. These similarities inspired us to adapt CTI for mentally ill prisoners. Our adaptation was designed to cope with unpredictable prison release times and the constraining effects of criminal justice procedures on the ability to plan for release, provide resources, such as accommodation, and to arrange suitable contact with community mental health services. Subsequently we carried out a small trial of CTI for men with SMI, discharged from two UK prisons[22]. We found CTI to be feasible, despite the legal and procedural issues, and acceptable to prisoners, in terms of their satisfaction with increased levels of support.

Aims

The primary aims of the project are to establish whether a specific model of case management, Critical Time Intervention (CTI), is effective in:

(1) improving engagement with health and social care services;
(2) reducing mental health hospital admissions;
(3) reducing re-offending; and
(4) increasing community tenure through reducing time in prison

among released adult male prisoners with severe and enduring mental illness (SMI).

The secondary aims are:

(5) to establish the cost-effectiveness of CTI for this client group;
(6) to develop service model manuals and training materials to support the implementation of CTI across CJS agencies and NHS sites; and
(7) to facilitate and promote active service user, CJS and NHS staff participation in the research work programme, thus encouraging greater engagement between the academic community of researchers, the practice community of healthcare and CJS staff and the users of CJS and generic based healthcare services.

Methods

Participants: 200 men with SMI. For this study, SMI is defined as major depressive disorder, hypomania, bipolar disorder and/or any form of psychosis including schizophrenia, schizoaffective disorder and any other non-affective, non-organic psychosis.

Inclusion Criteria: To be eligible for inclusion, participants must be:

(i) Severely mentally ill and clients of prison in-reach mental health services

(ii) Male

(iii) To be discharged from prison within the study period

Setting: Eleven prisons in England and Wales.

Design: Randomised controlled trial: individuals will be randomised to CTI or treatment as usual (TAU).

Recruitment: Participants are men with SMI under the care of prison in-reach services at participating prisons. We will seek informed consent for their inclusion in the study, if their known release date (convicted prisoners) or likely release date (un-convicted), is within six months of study recruitment. Release dates for un-convicted prisoners will be predicted using the algorithm based on length of stay and offence type developed during the feasibility study[22].

Randomisation: Randomisation will be undertaken by the Clinical Trials Unit (CTU), using an online system. Once consent has been taken and eligibility established, individual participants will be randomised by block randomisation, stratified by prison. Data will be entered onto the online InferMed MACRO data entry system, hosted at the CTU. The system is compliant with Good Clinical Practice (GCP), with a full audit trail, data entry and monitoring roles, and formal database lock functionality.

Service model: CTI is a comprehensive case management model, focussing on primary care, mental health, substance misuse, accommodation, financial and social support needs. CTI comprises four phases: the initial phase comprises engagement and care planning conducted before release, followed by three phases post-discharge, during which engagement with receiving community services is established, followed by withdrawal of the CTI manager.

In the feasibility trial, we produced a training intervention manual which will be used to train the CTI managers. For the duration of the study, each mental health in-reach team will designate one member of the team as a CTI manager. The CTI manager will operate a caseload comprising CTI patients only to ensure treatment fidelity and to avoid contamination of TAU. The other members of the in-reach team will provide care for TAU participants. The CTI managers will receive weekly clinical supervision from a clinician independent of the research team, experienced in ACT and trained in CTI. Fidelity data will be measured on a

scale developed by SC (personal communication) at three-monthly intervals by the research team.

Baseline assessments

At baseline all participants will be seen by a member of the research team and the following information collected;

(i) The Operational Criteria Checklist for Psychotic and Affective Illness (OPCRIT) will be used to obtain an axis I diagnosis.

(ii) Structured Clinical Interview for DSM-IV Personality Disorders (SCID-II): The SCID-II is a semi-structured interview for the assessment of Personality Disorders. The first part consists of eight open questions on the patient's general behaviour, interpersonal relationships, and self-reflective abilities. The second part has 140 items to be scored as 1 (absent), 2 (subthreshold), or 3 (threshold).

(iii) The Michigan Alcohol Screening Test (MAST): The MAST consists of 24 yes/no questions pertaining to lifetime use of alcohol. Each item is scored 0 or 1, with scores of 10 or more indicating evidence of having had a severe drinking problem at some point in one's life.

(iv) The Drug Abuse Screening Test (DAST): The DAST is similar in design to the MAST. It consists of 20 yes/no questions, each scored 0 or 1. Scores of 11 or more indicate substantial problems with drug abuse

(v) Adapted Client Services Receipt Inventory (CSRI): Developed from the CSRI, a proforma designed for the purposes of this study which includes 11 demographic items and 20 service contact items.

Measurement of outcomes and costs:

The primary outcome measure will be engagement with mental health services at six weeks post-discharge. Engagement is defined as being currently in receipt of an appropriate level of mental healthcare, defined as (i) having an allocated care co-ordinator and care plan; (ii) receiving appropriate medical treatment for mental health problems; and (iii) in regular, planned contact with their care co-ordinator. We will use a proforma designed for the feasibility study to gather these data. Secondary outcome measures will be engagement with mental health services at six and 12 months post intervention (cases; equivalent time for controls); number of days in hospital, including any detention under the Mental Health Act; and CJS contact and re-conviction rates, comparing data from 12 months before the recent period of imprisonment with the 12 months post-release, using the Police National Computer (PNC). Community tenure will

be calculated by adding the number of days in hospital to days in prison. The unit cost of the new service, costs of service use and estimated costs of crime will be compared between the CTI and TAU groups.

The costs of the intervention will be calculated based on (i) amount of time spent by CTI managers with participants plus time spent undertaking training and supervision combined with (ii) unit costs of CTI manager time, training and supervision. These unit costs will be derived from information on training, salaries, overheads, capital costs, and activity levels (e.g. number of service users seen, ratio of time spent with users and other associated duties). The use of other services will be measured utilising a proforma developed from the Client Services Receipt Inventory[23] (CSRI), combined with additional service use data from national NHS databases which record units of clinical activity. Service use included will consist of primary and secondary healthcare contacts, social care contacts and contacts with the CJS. The costs of these will be estimated by combining service use data with relevant unit cost information[24]. Costs of crimes committed will be estimated using Home Office data [25]. Total costs during the follow-up period will be compared between the CTI and TAU groups. Costs are usually skewed and therefore bootstrap methods will be used. Predictors of costs will be identified using regression models with independent variables chosen from clinical and demographic characteristics. Cost-effectiveness will be estimated by combining the total costs with reconviction rates.

Analysis

CMHT contact rates at six weeks, six months and 12 months and reconviction rates at 12 months will be compared between CTI and TAU groups using chi-square tests, logistic regression and survival analysis techniques. A longitudinal analysis of engagement over time since release will be conducted using cross-sectional time series methods (linear or logistic, as appropriate). Comparisons will adjust for variables expected to be associated with engagement and reconviction respectively.

Qualitative examination of "what works"

Purposive Sample: We will interview about 30 prisoners (15 CTI; 15 TAU), key mental health in-reach staff and community mental health team staff who had contact with clients post-release. Our previous work suggests that a range of professional groups are involved in the crucial transition between prison and community. This research will enable us to identify these groups, roles and responsibilities and inter-professional boundaries. Accordingly, we are not able to say exactly how many professionals will be interviewed but anticipate our sample will comprise around 10 in-reach and 10 community staff. The number of interviews with prisoners and staff will be determined by theme saturation.

Procedure: Prisoners will be interviewed prior, and subsequent, to discharge. Interviews will be orientated towards identifying: episodes of self and professionally defined need; and responses to, and support for, those needs whilst in prison and post-discharge.

Prison in-reach staff, including the CTI managers and community mental health team staff with principle responsibility for care will be interviewed about the needs of discharged prisoners; personal, professional, structural and organisational barriers and facilitators to continuity of care; specific elements of CTI which were judged most valuable by staff and clients; and lessons learnt which would valuably inform the generalisability and roll-out of the care model. The interviews will be semi-structured.

Analysis - All interviews will be transcribed verbatim and analysed thematically. A number of themes will be generated and elaborated using aspects of constant comparative methods[26]. Using components related to help-seeking and continuity of care, a typology of pre and post discharge pathways will be constructed from the data generated by the diaries and interviews. NVivo 8 software will be used to facilitate data management and analysis.

Project Management and Trial Governance

We will establish an overall steering committee, augmented by two specifically tasked work groups. The over-arching steering committee will have an independent chair and be responsible for overseeing ethical issues, data monitoring, financial probity and trial fidelity. The steering committee will meet every 6 months throughout the study. We will make use of phone and video conferencing to trouble shoot issues, as required, in between full meetings.
A separate project management work-group will review progress, timelines and costs. This project management group will meet quarterly throughout the study. A work-group established in the final 12 months of the project, comprising services users, staff from the CJS and NHS, policy makers and academics will specifically review the study findings, make recommendations for improvements to the new service based upon emerging evidence. This group will assist with the development of a service manual and associated training materials for use across the CJS and NHS, supporting targeted dissemination of appropriate materials to a variety of stakeholder groups through a variety of media.

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