# PHYSICAL HEALTH CHECKS IN SERIOUS MENTAL ILLNESS: A PROGRAMME OF RESEARCH IN SECONDARY CARE

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## Dedications

To Ian, Keziah and for my dad George.

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# Abstract

## Background

The physical health of people with serious mental illness [SMI] represents a significant public health challenge. It is estimated that they have a mortality rate two to three times greater than in the general population and the mortality gap is widening. Although suicide makes a significant contribution, cardiovascular disease [CVD] is the primary cause of death. A higher than expected prevalence of physical comorbidities in people with SMI has been identified in almost every system organ class [SOC] of the body with considerable overlap between them. This indicates multiple genetic, environmental, psychological, social, behavioural and system (of care) risk factors. A lower than expected incidence of comorbidities in the health records of people with SMI in primary and secondary care in the United Kingdom [UK] points to considerable under-diagnosis and treatment and presents an opportunity for intervention. There remains a paucity of evidence to support interventions that can be successfully implemented to make a difference to physical health outcomes in this vulnerable population.

The SMI Health Improvement Profile [HIP] was developed by the author and two colleagues as a complex but pragmatic intervention to target physical wellbeing in SMI through the existing role of the mental health nurse in secondary care. The HIP Programme (the HIP and HIP training) is intended to support the mental health nurse working with people with SMI to undertake a structured health check and negotiate and implement an individualised physical health care plan as a result.

## Aim

The aim of this research is to enable mental health nurses in secondary care to address the physical health needs of people with SMI by implementing a nurse-led structured physical health check and care planning process.

## Methods

This project used a programme of research to evaluate the impact of the HIP Programme on care processes and patient outcomes that included:

1. A systematic review of the efficacy of educational interventions for healthcare professionals.
2. Description of the development of the HIP Programme and a pilot study to test the clinical utility and effectiveness of the HIP Programme in 31 patients in a nurse-led outpatient clinic.
3. A clinical audit of the use of the HIP in 108 patients.
4. A cluster RCT of the HIP Programme across four National Health Service [NHS] sites.
5. A process observation in a subsample of patient and nurse participants from the cluster randomised controlled trial.
6. Evaluation of evidence of impact from national and international dissemination of the HIP and the HIP Programme.

## Results

1. The systematic review identified that there was no evidence examining how to train healthcare professionals to deliver a structured health check for people with serious mental illness [SMI].
2. The pilot study identified that the HIP was acceptable to people with SMI and healthcare professionals and that two mental health nurses could successfully implement the HIP following brief training.
3. The audit showed that it was possible to identify comorbidities in people with SMI using the structured health check in secondary care and that change in health behaviours and outcomes was possible.
4. The cluster RCT in community mental health teams across four NHS sites demonstrated no difference in health outcomes between HIP Programme and Treatment As Usual [TAU] patients at 12 months. Despite acceptable levels of patient attrition in the trial, rates of implementation of the HIP by nurse participants was very low.
5. The process evaluation highlighted the complexity of the processes we were trying to change. Barriers included service redesign and resource issues coupled with the time taken to complete the HIP and care plan. Nurse participants reported that they did not work with the same patients with SMI for long enough to follow through a (12 month) plan of physical health checks and intervention. There was a perception of structured physical health checks and care as a (new) extension to

an already pressured role where mental health risk assessment and management takes priority over physical health risk.

6. The HIP is being used widely in practice but this is largely in inpatient services. Where it has been repeated at 12 months, improvements in some metabolic parameters have been seen.

**Discussion**

The need for better care for the physical health of people with SMIs is evident. This program of research developed a package of training and tool to support a structured health check and care planning process for people with SMI in secondary care. The cluster RCT did not demonstrate benefit on patient (quality of life) outcomes. Substantial structural barriers prevented the patients from receiving the intervention from the mental health nurses involved in the trial, despite the positive attitude of the nurse participants towards the importance of a physical health care role. Despite this disappointing finding the intervention is being used in practice across the United Kingdom [UK] and internationally with demonstrated benefits, including the achievement of commissioning targets for health screening and signs of improvement in some outcomes where it has been used in the same person over time. This programme of research demonstrates the challenge of conducting useful RCTs in rapidly changing service environments in the NHS. Future research should develop the intervention beyond the nurse and patient dyad to target the system barriers and levers to implementation.

# Table of Contents

## TABLE OF TABLES



## TABLE OF FIGURES

## DECLARATION

No portion of this work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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## THE AUTHOR

I trained as a registered mental health nurse at St George's Hospital School of Nursing and Springfield Hospital in South London, qualifying in 1986. I worked in a variety of community and hospital settings until 1993 when my daughter was born. After starting a part time degree I took up a post as Research Nurse in the Department of Psychiatry at the University of Hull Post Graduate Medical School in 1995, working with Professor Anne Mortimer. In this role I became interested in the contrast between the quality of medication management received by study participants compared to usual care. The focus of the research project for my degree dissertation was the role of the mental health nurse in medication management. Supported by a Florence Nightingale Research Scholarship, I conducted a survey of mental health nurses working in acute inpatient unites across Hull and East Yorkshire that demonstrated motivation for the role but a lack of education or support to achieve it. The local NHS Trust then funded me to implement a project to train nurses in medication management and set and audit standards for medication management. I contacted the three UK mental health nurse academics publishing in the area of medication management in mental health nursing at the end of the nineties, Richard Gray, Neil Harris and Joanna Bennett and I undertook Richard's train the trainer Medication Management course in 1999. I obtained and adapted resources from two very generous people who were trying to make a difference; a neuropharmacologist who taught the first cohort of mental health nurse prescribers in Stafford and James Turner, a service manager in Sheffield who had implemented a medication management project in acute inpatient care known as 'Medicines with Respect". I worked with service users from Mind to evaluate the project.

In 2000 I moved to work as a lecturer in clinical nursing at the University of Hull where I am now an Associate Dean in the Faculty of Health and Social Care. I set up a local medication management network to support the nurses I trained to implement their ideas for practice development and facilitated this for 8 years. In 2004, in recognition of a need for regional support I founded the M62 Network. As a result of collaboration through this network, a stepped approach to medication management nurse education is recommended and adopted by several HEEs and provider organisations across Yorkshire and Humber.

I started my career in services that were transitioning from institutional to community care in the early 1980's. Although there was much that was wrong in the old hospitals that I would never want to return to I witnessed the negative consequences of community care for many vulnerable people with psychotic diagnoses first hand. I thought I understood (or at least accepted) the focus of most mental health nurses work on the assessment and

management of the risk of violence and suicide. I suspected the so called “control-care paradox” within mental health care was working against the support of people with long-term psychotic disorders to live long and fulfilling lives. Management of the risk of violence and suicide by its very nature focuses on immediate risk rather than in working over the longer term to support positive physical and mental health outcomes.

I was personally motivated to do something to try and make a difference by the widening mortality gap between people with SMI and those in the general population. My students reported that early death from cardiovascular disease in their SMI patients was a far-too common experience that they felt uncomfortable about and wanted to change. I was not aware of any focus on the assessment of physical health risks in mental health nursing other than those tools designed to assess for the risk of falls in the elderly and the risk of loss of skin integrity (pressure sores). In adults, I was only aware of tools to assess medication side effects. There was a growing recognition of the need to address the unacceptable comorbidity and mortality in SMI in health policy and mental health nurse education standards. Students were required to demonstrate competency in areas of practice that qualified nurse mentors struggled with themselves.

There were no physical health care texts in 2008 aimed at mental health nurses and information had to be drawn from a variety of sources. Survey research indicated that mental health nurses felt ill equipped in terms of knowledge but wanted to include physical health care in their work. I hoped that a knowledge and decision making tool in an accessible format would enable this to happen.

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## ABBREVIATIONS

| | |
|---|---|
| ASS | Anticonvulsant sensitivity syndrome |
| BMI | Body mass index |
| BPD | Bipolar Disorder |
| CEAC | Cost-effectiveness acceptability curve |
| CHD | Coronary heart disease |
| CI | Confidence Interval |
| CLAHRC | NIHR Collaboration for Leadership in Applied Health Research & Care |
| CMHN | Community Mental Health Nurse |
| CMHT | Community Mental Health Team |
| CONSORT | Consolidated Standards of Reporting Trials |
| COPD | Chronic Obstructive Pulmonary Disease |
| COREQ | Consolidated criteria for reporting qualitative research standards |
| CPA | Care Programme Approach |
| CQUIN | Commissioning for Quality and Innnovation |
| CRF | Case Record Form |
| CRSI | Client Service Receipt Iatrogenic |
| CTRU | Clinical Trials Research Unit |
| CVD | Cardiovascular disease |
| DALYs | Disability Life Adjusted Years |
| DKA | Diabetic ketoacidosis |
| DM | Diabetes mellitus |
| DOH | Department of Health |
| DSM-IV | The Diagnostic and Statistical Manual of Mental Disorders (fourth edition) |

| | |
|---|---|
| ECG | Electrocardiogram |
| EQ-5D | EuroQol 5 Dimensions questionnaire |
| EQ-5D VAS | EuroQol 5 Dimensions questionnaire (visual analogue scale) |
| HBC | Hepatitis C |
| HBV | Hepatitis B |
| HDL | High-density lipoprotein |
| HIP | Health Improvement Profile |
| HIV/AIDS | Human immunodeficiency virus/acquired immunodeficiency syndrome |
| HPA | Hypothalmic-pituitary-adrenal axis |
| HRU | Health Resource Use |
| IBS | Irritable bowel syndrome |
| ICD-10 | International Statistical Classification of Diseases and Related Health Problems 10th Revision |
| IDF | International Diabetes Federation |
| IQR | Interquartile range |
| IRR | Incidence rate ratio |
| LDL | Low-density lipoprotein |
| LTP | Lifetime prevalence |
| MCS | Mental component summary score |
| MDMA | 3,4-methylenedioxy-N-methylamfetamine |
| MetS | Metabolic syndrome |
| MHN | Mental Health Nurse |
| MHRN | Mental Health Research Network |
| MI | Myocardial infarction |
| MOS | Medical Outcome Study |

| | |
|---|---|
| MR | Mortality rate |
| MRR | Mortality rate ratio |
| NAS | National Audit of Schizophrenia |
| NCEP | National Cholesterol Education Program |
| NESARC | National Epidemiologic Survey on Alcohol and Related Conditions |
| NHS | National Health Service |
| NICE | National Institute of Health and Care Excellence |
| NIHR | National Institute of Health Research |
| NMS | Neuroleptic malignancy syndrome |
| OA | Osteoarthritis |
| OP | Osteoporosis |
| OR | Odds Ratio |
| OSA | Obstructive sleep apnea |
| PALS | Patient Advice and Liaison Service |
| PCS | Physical component summary score |
| PHASe | Mental Health Nurse Physical Health Attitude Scale |
| PID | Participant Identification Number |
| PIF | Psychosis in Finland study |
| PPI | Public and Patient Involvement |
| PVD | Peripheral vascular disease |
| QOF | Quality and Outcomes Framework |
| QoL | Quality of Life |
| QRISK©2 | QRISK cardiovascular risk prediction tool |
| RCT | Randomised controlled trial |
| REC | Research Ethics Committee |

| | |
|---|---|
| RISE | Research Initiative into Schizophrenia Epidemiology |
| RR | Risk ratio |
| SCD | Sudden cardiac death |
| SF-36v2 | Short form health survey version 2 |
| SF-6D | Short form health survey six dimenions |
| SMI | Serious Mental Illness |
| SMR | Standard mortality ratio |
| SNS | Sympathetic nervous system |
| SOC | System Organ Class |
| SPSS | Software package for statistical analysis |
| SS | Serotonin syndrome |
| SSRI | Selective serotonin re-uptake inhibitors |
| TAU | Treatment as usual |
| TLM | Traffic Light Method for Somatic Screening and Lifestyle |
| TMG | Trial Management Group |
| TSC | Trial Steering Committee |
| UEA | The University of East Anglia |
| UK | United Kingdom |
| WHO | World Health Organisation |
| YLLs | Years of life lost |

# Chapter One: Serious Mental Illness

## Mental health and illness

Mental health is “a state of well-being in which the individual realises his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community.” (World Health Organisation, 2013a). Mental illness, also called mental or psychiatric disorder, is a diagnosable condition that significantly interferes with an individual's cognitive, emotional or social abilities. Mental and substance use disorders taken together account for about 7·4% of the global disease burden worldwide and were ranked 5$^{th}$ after the human immunodeficiency virus/acquired immunodeficiency syndrome [HIV/AIDS], tuberculosis, diabetes and transport injuries in the latest 2010 WHO survey (Whiteford et al.).

## Serious mental illness

There are a number of different definitions of serious mental illness in the literature. The International Statistical Classification of Diseases and Related Health Problems 10th Revision [ICD-10] is the official classification system for diagnosis used by the majority of United Nations member states for epidemiological and quality assurance purposes and to compile national mortality and morbidity statistics (World Health Organisation, 2007). In this thesis the term serious mental illness [SMI] is used to denote adults over 18 years with an established diagnosis of either schizophrenia, schizoaffective or bipolar affective disorder according to ICD-10.

## Schizophrenia

Schizophrenia is a persistent multidimensional disorder characterised by a range of symptoms that can be clustered into positive (psychotic), negative, cognitive and affective sets or dimensions (Van Os J et al., 2010). These symptoms are summarized in Figure 1.1. These symptoms affect function in major areas of the person’s life such as occupation, relationships and self-care. They can be expressed differently in different individuals and in the same individuals over time.

**Figure 1:1 Symptom Domains of Schizophrenia**

| Symptom Domain | Examples |
|---|---|
| **Positive (psychotic) symptoms** | Delusions<br>Hallucinations<br>Thought disorder<br>Distorted speech or behaviour<br>Disorganised speech or behaviour<br>Catatonic behaviour<br>Agitation |
| **Negative symptoms** | Blunted affect<br>Emotional withdrawal<br>Poor rapport<br>Passivity phenomena<br>Apathetic social withdrawal<br>Anhedonia<br>Alogia<br>Stereotypical thinking and behaviours |
| **Cognitive symptoms** | Problems with executive function e.g. problems directing and sustaining attention, difficulty prioritising and solving problems.<br>Memory and learning problems |
| **Affective symptoms** | Depressed mood<br>Anxious mood<br>Guilt<br>Tension<br>Irritability |

Adapted from (Stahl, 2000)

The heterogeneity of schizophrenia presents many challenges to clinicians and researchers leading to doubts about the existence of a unified underlying disease state, with some authors considering it a social construct ((Walker 2006, Szazs 1961)).

Schizophrenia is classified as a mental or behavioral disorder in ICD-10 and allocated codes F20.0-F20.9 with nine potential subcategories depending on symptom clusters and course. These are paranoid, hebephrenic, catatonic, undifferentiated, post schizophrenic depression, residual, simple, other and unspecified. Similar disorders developing in the presence of organic brain disease or psychoactive substance intoxication are excluded. Please see Figure 2 for ICD-10 diagnostic criteria.

The aetiology of schizophrenia is complex with a strong genetic influence hypothesised to interact with environmental risk factors. The hereditary component of schizophrenia is well established with a 48% risk of developing schizophrenia in monozygotic twins where one has the disorder. Risk in family members increases with the degree of biological relatedness (Gottesman, 1991). A shared familial environment cannot fully explain this as adoption studies indicate a similar prevalence to that in first degree relatives (Kety et al., 1994). Environmental risk factors include developmental trauma and the exposure of the brain to chemicals and stress (particularly where there is neglect, abuse, victimisation and/or social exclusion) (van Os et al., 2010).

A relatively low rate of new cases of schizophrenia over time (incidence) is reported. The most recent published systematic review and recalculation of 133,639 international cases by the Research Initiative into Schizophrenia Epidemiology [RISE] report a median value of 18.3 per 100,000 persons per year with a threefold higher rate in men, although when samples are stratified by age of onset the picture is complicated. An increased male incidence is detected in samples aged <40 years (Incidence rate ratio [IRR] 0.55, Interquartile range [IQR] 0.45-0.75), between 40 and 59 years no difference is detected and ≥ 60 years the trend becomes reversed with a greater incidence of new cases reported in women (IRR 1.55, IQR 0.92-2.19) (van der Werf et al., 2014). A rigorous systematic review of 188 studies covering 46 countries concluded that for every 1,000 people in the international population a median of 4.6 will have the disorder at any specific time (point prevalence), 4 people will have received the diagnosis at some time and 7.2 people risk developing it over their lifetime (lifetime morbid risk) (Saha et al., 2005).

**Figure 1:2 ICD-10 Diagnostic criteria for schizophrenia**

| A minimum of one very clear symptom belonging to any one of groups 1-4 or symptoms from at least two of the groups 5-9 should have been clearly present for most of the time during a period of one month or more | |
|---|---|
| Groups | |
| 1 | Thought echo, thought insertion or withdrawal and thought broadcasting |
| 2 | Delusions of control, influence or passivity, clearly referred to body or limb movements or specific thoughts, actions or sensations: delusional perception. |
| 3 | Hallucinatory voices giving a running commentary on the patient's behaviour or discussing the patient among themselves, or other types of hallucinatory voices coming from some part of the body. |
| 4 | Persistent delusions of other kinds that are culturally inappropriate and completely impossible, such as religious or political identity, or superhuman powers and abilities (e.g. being able to control the weather or being in communication with aliens from another world). |
| 5 | Persistent hallucinations in any modality, when accompanied either by fleeting or half-formed delusions without clear affective content or by persistent over-valued ideas, or when occurring every day for weeks or months on end. |
| 6 | Breaks or interpolations in the train of thought, resulting in incoherence or irrelevant speech, or neologisms. |
| 7 | Catatonic behaviour, such as excitement, posturing or waxy flexibility, negativism, mutism and stupor. |
| 8 | "Negative" symptoms such as marked apathy, paucity of speech and blunting or incongruity of emotional responses, usually resulting in social withdrawal and lowering of social performance; it must be clear that these are not due to depression or neuroleptic medication. |
| 9 | A significant and consistent change in the overall quality of some aspects of personal behaviour, manifest as loss of interest, aimlessness, idleness, a self-absorbed attitude and social withdrawal. |

Burden of disease is measured globally using Disability Life Adjusted Years [DALYs] that represents a sum of the years of life lost and the years living with a disability as a result of a condition or injury (Murray et al., 2012a). Despite schizophrenia being a relatively rare disorder, disease burden in DALYs is high. In 2010 schizophrenia accounted for 218 DALYs per 100,000 population (95% CI 142-296) and the 43rd ranked leading cause of disability worldwide (Murray et al., 2012b). Of the other mental and behavioural disorders only major depression, anxiety disorders, drug use disorders and alcohol use disorders rank in the top 50 above schizophrenia (11th, 26th, 31st and 35th respectively).

The annual economic burden of schizophrenia was estimated to be £6.7 billion in 2004/05 in England (Mangalore and Knapp, 2007). Projection to 2011/12, costs increased this to £11.8 billion per year. Average societal costs of £60,000 were calculated (e.g. due to unemployment and early mortality) plus £36,000 to the public sector per person per year (Andrew et al., 2012). The largest proportion of the cost of treating schizophrenia relates to relapse and the cost of inpatient care (Hong et al., 2009).

The high disease and economic burden of schizophrenia is probably linked to two important features: a) Onset and greatest deterioration usually occurs in early adulthood (Schultz et al., 1997) and therefore has a significant impact on occupational attainment, as well as the ability to form and maintain relationships; b) Despite treatment with medication with proven efficacy, approximately two-thirds of affected individuals continue to have symptoms (Kane, 1989). Positive and disorganised symptoms tend to improve over time but negative and cognitive symptoms may worsen, particularly in institutional environments and as a result of long-term treatment with most types of antipsychotic medication (Karim et al., 2005). A longer duration before treatment of the first episode and the number of relapses is correlated with worse outcomes (Lieberman et al., 1993). Negative and cognitive symptoms arguably have the greatest impact on function and disability. The pattern of worsening negative symptoms is more common in men across the life course, whereas in women this deterioration is observed to occur much later in life (Gur et al., 1996).

## Schizoaffective disorder

Schizoaffective disorder is an episodic disorder in which both affective and schizophrenic symptoms are prominent but do not justify a diagnosis of either schizophrenia or depressive or manic episodes (World Health Organisation, 2007). It is allocated ICD-10 codes F25.0-F25.2, F20.8 and F20.9 with five potential subcategories. These depend on the type of mood state that predominates and illness course (manic type, depressive type, mixed type, other and unspecified).

In what appears to be the only study to report the lifetime prevalence [LTP] of psychotic disorders separately using robust methods for diagnosis the Psychosis in Finland [PIF] Study identified participants from the Finnish Health 2000 (general population) survey. A representative sample of 8,028 persons ≥30 years of age were randomly selected using a 2-stage stratified clustering method. Those screening positive for psychosis from this sample as a result of either self-report, semi-structured interviews, national hospital discharge and insurance registers, and/or case notes were reassessed using the research version of the Structured Clinical Interview for DSM-IV. A best estimate diagnosis was made by agreement of three psychiatrists and/or psychologists retrospectively using all available baseline data. This resulted in 692 people in the final best estimate diagnosis arm of the study. The results for schizophrenia (n=67) were similar to other prevalence estimates at 0.87 per 100,000 (95% CI 0.68-1.1) rising to 1% when non-responders were included. Lifetime prevalence for schizoaffective disorder (n=27) was 0.32 (0.21-0.46) and bipolar 1 disorder (n=20) 0.24 (0.16-0.37). Women were significantly more likely to have a diagnosis of schizoaffective disorder than men ($p < 0.05$). When LTP was compared across age bands there were no men at all in the 30-39 year band for schizoaffective disorder.

### Bipolar affective disorder

Bipolar affective disorder (also known as bipolar disorder or manic depressive disorder) is characterised by two or more episodes in which mood and activity levels are significantly disturbed causing significant personal distress or social dysfunction (World Health Organisation, 2007). There can be an elevation of mood, increased energy and activity (hypomania or mania) on some occasions and a lowering of mood, decreased energy and activity (depression) on others. Hypomania and mania are differentiated based on their effects on function with hypomanic symptoms often valued as positive by the person. Episodes can be predominantly in one direction or another (manic or depressed) or cycle between mood states. There are a number of types of bipolar affective disorders identified in ICD-10, see Figure 1.3 for a summary. In DSM-IV there is a differentiation of bipolar spectrum disorders into bipolar 1 disorder (where mania predominates or there is a history of at least one manic episode) and bipolar II disorder (where there is or has only been hypomania) (American Psychiatric Association, 1994).

A recent systematic review of prevalence in adults identified 18 studies reporting lifetime prevalence ranging from 0.1 to 7.5% in bipolar disorder and 2.4 to 15.1% in the broader category of bipolar spectrum disorder (Dell'Aglio et al.). The incidence of bipolar disorder is reported as 2.6 to 20.0 per 100,000 per year (Lloyd and Jones, 2002). In a further study where diagnostic criteria was applied prospectively to 75 patients from three UK NHS secondary care sites, the incidence was 4.0 per 100,000 population (95% CI 3.2-5.1)

(Lloyd et al., 2005). These differences may be related to the presence or absence of sub-threshold criteria on diagnosis. Depressive symptoms are most likely to be presented to clinicians. Unless the presence/absence and frequency of hypomanic or manic symptoms are uncovered through specific enquiry, the risk of misdiagnosis is significant.

Gender differences are largely found to be absent in prevalence studies of bipolar disorder with the exception of an increased lifetime prevalence in men, but only when manic presentation is differentiated from bipolar I disorder ((Szádóczky et al., 1998)). In bipolar II disorder the evidence is equivocal with some studies finding twice the lifetime prevalence of bipolar-II disorder and hypomania in women and others finding no difference at all between genders (Diflorio and Jones, 2010).

Figure 1:3 ICD-10 Diagnostic criteria for bipolar affective disorders

| **ICD-10 Code** | **Diagnostic features** | |
|---|---|---|
| **F31.0** | The current episode meets the criteria for hypomania. | AND for each there has been at least one other affective episode in the past, meeting the criteria for hypomanic or manic episode, depressive episode or mixed episode. |
| **F31.1** | The current episode meets the criteria for mania without psychotic symptoms. | |
| **F31.2** | The current episode meets the criteria for mania with psychotic symptoms. | |
| **F31.3** | The current episode meets the criteria for a depressive episode of either mild or moderate severity. | |
| **F31.4** | The current episode meets the criteria for a severe depressive episode without psychotic symptom. | |
| **F31.5** | The current episode meets the criteria for a severe depressive episode with psychotic symptom. | |
| **F31.6** | The current episode is characterised by either a mixture or a rapid alteration (i.e. within a few hours) of hypomanic, manic ands depressive symptoms. Both manic and depressive symptoms must be prominent most of the time over at least two weeks. | |

Age of onset is thought to peak in late adolescence, a time when diagnosis is difficult and may be actively avoided. Early onset patients that present with depression face a considerable time-delay before first diagnosis. In one survey of 600 people with a diagnosis of BPD, one third reported they had sought professional help within a year of

the first onset of symptoms with 69% (414) receiving an incorrect diagnosis (most frequently unipolar depression). Just over a third reported waiting 10 years or more before receiving an accurate diagnosis (Hirschfeld et al., 2003). It has been suggested that between a half and two thirds of all unipolar depression diagnoses are bipolar II disorder (Akiskal et al., 2000). Substance and alcohol misuse is also highly prevalent and highlights another example where the presenting 'problem' becomes the primary diagnosis. There is also considerable crossover between bipolar disorder (particularly cyclothymia) and borderline personality disorder.

A strong link between postpartum psychosis (that typically occurs in the first month after childbirth) and bipolar disorder is increasingly becoming evident, blurring diagnostic boundaries. The risk of developing postpartum psychosis is substantially increased in women with bipolar disorder, particularly where there is family history of postnatal bipolar episodes (Jones and Craddock, 2001).

Like schizophrenia, the aetiology of bipolar disorder is thought to include a genetic predisposition that interacts with environmental and neurodevelopmental risk factors. The annual socioeconomic burden of bipolar disorder in the UK was estimated to be £2 billion in 1991-2000. Ten percent of this cost is attributable to NHS resource use, 4% to non-health-care resource use and 86% to indirect costs (Das Gupta and Guest, 2002). The authors of this study used a prevalence estimate of 0.5% (297,000 people with the disorder), towards the lowest end of the range reported in the literature. Although it is not possible to compare this study directly with those in schizophrenia, the difference is striking. This could reflect a variety of factors and/or differences between the two disorders. It could be due to the low rates of diagnosis and treatment resulting in a much lower cost of medication and inpatient treatment in bipolar disorder. It could reflect a bias on the societal and health costs of mania, where the costs of bipolar depression are more hidden. The costs of comorbidity were not included although this is likely to be considerable, particularly that related to drug and alcohol use. It could reflect a lower cost due to the different treatment course that sometimes (but not always) leaves people cognitively intact and able to function, work and maintain relationships between episodes.

## Chapter Summary

Schizophrenia and schizoaffective disorders are rare. The prevalence of bipolar affective disorder is less certain. All three disorders have a very high socioeconomic and disease burden due to their early age of onset, symptom course, management and associated comorbidities.

## Chapter Two: Physical comorbidity in serious mental illness

There is a greater prevalence of a range of physical comorbidities in SMI with the highest prevalence reports in schizophrenia. This could be a feature of the studies focussing exclusively on this population and/or the smaller sub-group sample sizes nested within broader SMI datasets. There are no studies into comorbidity in schizoaffective disorder alone, but studies into bipolar spectrum disorders have increased in recent years. Two cross-sectional studies of primary care records for approximately a third of the population in Scotland demonstrated a significant association of having at least one comorbidity with schizophrenia (OR 1.21, 95% CI 1.16-1.27) and bipolar disorder (OR 1.27, 95% CI 1.16-1.39) with greater odds for multiple comorbidities in both disorders (Smith et al., 2013a, Smith et al., 2013b).

Comorbidities where there is evidence of increased prevalence or incidence in SMI are organised by their SOC and are summarised in Table 1. They are discussed in this chapter and where comorbidity can be classified in more than one SOC, this is indicated in the table. Risks are discussed in detail later but where the comorbidity is largely explained by the risk factors these are introduced here.

**Table 2:1 Physical comorbidity by system organ class**

| System organ class | Schizophrenia | Bipolar affective disorder |
|---|---|---|
| **Infections and infestations** | Tuberculosis<br>Pneumonia<br>Hepatitis B and C**<br>HIV** | Hepatitis C**<br>HIV** |
| **Neoplasms** | Colon cancer (+/-)<br>Breast cancer (+/-) | |
| **Immune system disorders** | *HIV*** | *HIV***<br>*Psoriasis*<br>Rheumatoid arthritis (+/-)<br>Inflammatory Bowel Disease (+/-) |
| **Endocrine disorders** | *Hyperprolactinaemia** | Thyroid disease |
| **Metabolism and nutrition disorders** | Metabolic syndrome<br>Obesity, hyperlipidaemia, diabetes mellitus. | Metabolic syndrome<br>Obesity, hyperlipidaemia, diabetes mellitus. |
| **Nervous system disorders** | *Cerebrovascular disease*<br>Epilepsies<br>Parkinson' s disease/parkinsonism<br>Neuroleptic Malignancy Syndrome* | *Cerebrovascular disease*<br>Epilepsies<br>Parkinson' s disease/parkinsonism |
| **Eye disorders** | Blindness or low vision<br>Ocular adverse effects* | Blindness or low vision<br>Ocular adverse effects* |
| **Ear and Labyrinth disorders** | Severe hearing loss | |
| **Cardiac disorders** | Angina symptoms<br>Sudden cardiac death | |
| **Vascular disorders** | Peripheral vascular disease<br>Cerebrovascular events<br>*Hypertension* | Cerebrovascular events<br>*Hypertension* |
| **Respiratory disorders** | Impaired lung function<br>Chronic obstructive pulmonary disease<br>Asthma | Chronic obstructive pulmonary disease |
| **Gastrointestinal disorders** | Poor oral and dental health<br>Constipation<br>Inflammatory Bowel Syndrome | Poor oral and dental health<br>Constipation<br>Inflammatory Bowel Syndrome |

| System organ class | Schizophrenia | Bipolar affective disorder |
|---|---|---|
| **Hepatobilary disorders** | *Hepatitis B/C*** | *Hepatitis B/C*** |
| **Skin and subcutaneous tissue** | | Psoriasis* |
| **Musculoskeletal and connective tissue disorders** | Osteoporosis/decreased mineral bone density | |
| **Renal and urinary disorders** | Dehydration<br>Polydipsia | Dehydration<br>Chronic kidney disease<br>End stage renal disease* |
| **Pregnancy, peurperium and perinatal disorders** | Obstetric complications<br>Gestational diabetes (+/-)<br>Abnormal foetal growth | Obstetric complications<br><br>Low birth weight,<br>Congenital birth defects* (+/-) |
| **Reproductive system and breast disorders** | Hyperprolactinaemia*<br>Galactomastia, galactorrhea*<br>Menstrual problems (women)*<br>Arousal and orgasm problems (men)*<br>Low libido (men and women)<br>Low birth rate | <br><br><br><br><br><br>Low birth rate |
| **General disorders** | Neuropathic or psychogenic pain | Musculoskeletal, neuropathic or neurogenic pain |

*Italics* indicates comorbidities that are discussed in another system organ class

* = evidence from medication studies alone

** = only occurs where there is concurrent substance use

+/- = discrepant results

## Infections

*Bacterial infections*

Before the closure of large institutions, respiratory bacterial infections such as tuberculosis and pneumonia were the largest causes of mortality in SMI (Leucht et al., 2007). There are two reports of an increased prevalence of tuberculosis in schizophrenia from epidemiological studies of case registers in Nagasaki city and Oxford in the 1960's and 1970's (Ohta et al., 1988, Baldwin, 1979). Baldwin et al. identified an increased prevalence in patients before their admission to hospital but reports of increased incidence in single studies since the 1970's have all been associated with institutional or group-living environments ((Cavanaugh et al., 2012)).

*Viral infections*

There have been a number of reports of an increased prevalence of HIV in people with a very broad range reported in different epidemiological studies: 1.3- 2.9%, compared to 0.6% in the global population (Leucht et al., 2007). Authors reporting the highest and lowest prevalence statistics may have accessed higher or lower risk samples by studying predominantly urban or rural populations. A failure to adjust estimates for confounding demographic, lifestyle and socioeconomic risks (e.g. ethnicity, substance use, unsafe sexual practices, poverty) and/or low levels of HIV testing in SMI are also likely to have contributed to this variability. Interestingly, in bipolar disorder where substance use, hypersexuality and increased risk taking are features of the illness, increased prevalence for HIV has not been separately identified, although a general increase in the prevalence of sexually transmitted diseases has (Jones et al., 2004). One well conducted case record linkage study that drew SMI samples equally from populations known to be at high and low risk found 8 times the US general population prevalence(Rosenberg et al., 2001).. Importantly they found 75% of HIV positive individuals had a co-current substance use disorder More recently increased prevalence of HIV in SMI has been identified in dual diagnosis of SMI and substance use/dependence at levels that explain the risk (2.1 and 2.5 more likely respectively) and a much lower prevalence than the general population when substance use is absent (Prince et al., 2012).

Viral hepatitis is one infectious disease where increased rates above those in the general population have consistently been reported in SMI. In cross sectional surveys of primary care case records representing one third of the Scottish population, viral hepatitis was the highest recorded comorbidity for both schizophrenia and bipolar disorder (Smith et al., 2013a, Smith et al., 2013b). In the same case record linkage study in SMI discussed above rates of hepatitis B [HBV] were 5 times the US general population prevalence rate and hepatitis C [HBC] was 11 times more prevalent (Rosenberg et al., 2001). The much higher rate in HCV supports a strong link with substance use (particularly intravenous and

inhaled drug use) as HCV has the highest incidence of person-to-person transmission of any blood born virus (Garfein et al., 1996).

**Neoplasms**

There have been contradictory findings from studies into cancer in SMI, with some authors finding significantly increased prevalence rates, while others do not and some report less prevalence (De Hert et al., 2011b). Much of the evidence is weakened by small samples of convenience (e.g. hospital cohorts) and a failure to control for important potential confounding variables. There is some evidence for an increased prevalence of colorectal cancers (particularly colon cancer) in schizophrenia but evidence for breast cancer, cervical cancer and lung cancer is equivocal. Prostate cancer has consistently been found to have approximately 50% less incidence in schizophrenia than in the general population in hospital cohorts leading to speculation about inherent protective factors of the disorder or it's treatment (Dalton et al., 2005, Grinshpoon et al., 2005, Mortensen, 1994). In bipolar disorder there is no evidence for increased prevalence of any single cancer. Three large cross sectional studies of primary care records in the UK found no increased incidence of recorded diagnosis of any cancer in schizophrenia or bipolar disorder (Osborn et al., 2013, Smith et al., 2013b, Smith and Roberts, 2006). Lifestyle risk factors (e.g. smoking, obesity, alcohol use, HCV infection) would theoretically increase the rates of cancers, as would some adverse effects of medication. However, low levels of diagnosis and mortality from diseases that develop earlier in the patient's lifecycle (e.g. cardiovascular disease) may be important. One nested case-control study from a large primary care UK dataset that did find a significantly increased incidence of colon cancer in schizophrenia reported a high mean age of diagnosis in cases and controls (72 years) (Hippisley-Cox et al., 2007).

**Blood and lymphatic system disorders**

Blood dyscrasias can arise as result of adverse effects of many psychotropic medications but do not feature in the comorbidity literature.

**Immune system disorders**

There have been some reports of autoimmune inflammatory (rheumatoid) arthritis and inflammatory bowel diseases associated with bipolar disorder and, in contrast, a negative association with schizophrenia (Mors et al., 1999, Birgenheir et al., 2013). A number of studies have identified a lower prevalence of inflammatory arthritis and diverticular disease in people with schizophrenia than in general population controls. (Smith et al., 2012a; Smith et al., 2013b; Mors et al., 1999). However, prevalence of both these comorbidities was roughly equal to the general population controls in bipolar disorder (Mors et al., 1999). It has been suggested that antipsychotic medication may have anti-

inflammatory properties that explain the reduced risk in schizophrenia but these findings are still surprising when one considers the effects of obesity on development and prognosis of both conditions. In study of obese subjects with bipolar disorder from the National Epidemiologic Survey on Alcohol and Related Conditions [NESARC] in the US, obesity at baseline was positively associated with new diagnosis of arthritis (OR = 1.64, 95% CI: 1.07–2.52), although osteoarthritis was not differentiated from rheumatoid arthritis (Goldstein et al., 2013). It seems more likely that the case register studies highlight low rates of diagnosis.

**Endocrine disorders**

Investigations of thyroid hormone levels for differential diagnosis are routinely made in SMI. There is a long association of bipolar disorders with thyroid disease among clinical and epidemiological populations (Chakrabarti, 2011). An overlap in symptom expression and contribution of thyroid hormone dysregulation to the aetiology, course and expression of symptoms, alongside the development of comorbidities such as obesity, metabolic syndrome and cardiovascular disease makes the hypothalamo-pituitary-thyroid (HPT) axis an important focus for investigation in all psychotic disorders.

**Metabolism and nutrition disorders**

The metabolic syndrome is a cluster of cardiovascular risk factors including hypertension, central (abdominal) obesity, dyslipidaemia, insulin resistance and glucose intolerance (International Diabetes Federation, 2006). Prevalence of MetS varies globally with differences between ethnicities, genders and with increasing age, with prevalence rates ranging between 14.4%-31.8% (NCEP Expert Panel on Detection, 2002), (Ford et al., 2002, Tillin et al., 2005) .With the rise of obesity and diabetes mellitus across the world, a corresponding increase in these rates seems inevitable.

Metabolic syndrome has a complex aetiology but lifestyle factors such as smoking, diet, medication, hereditary factors and social deprivation are all recognised as important. Prevalence of MetS using ATP III definition is reported, from the most recent meta-analyses, as 32.8% in schizophrenia (N = 80 studies, n = 17005 patients, 95% CI = 30.0%–35.7%) and 29.9% in bipolar disorder (N=18, n=2,204; 95% CI=28.0–31.9) (Mitchell et al., 2011, Vancampfort et al., 2013b). When the results of studies that matched SMI patients to controls were analysed by the same authors, around two and a half times the general population prevalence in schizophrenia was identified and twice as many in bipolar disorder. It is not possible to directly compare prevalence between the two disorders as there was no adjustment for age or gender. However a lower prevalence of MetS at the beginning of the treatment course was identified that may be an important signal of the metabolic risks of treatment. This is supported by meta-analyses of untreated

and first episode patients with schizophrenia that showed rates of MetS of around 10%, similar to prevalence in the general population (Mitchell et al., 2012)

In the recent MetS meta-analyses hypertension prevalence was reported at 38.7% in schizophrenia (N = 72; n = 18 657, 95% CI = 35.6%–41.9%) and 47.1% in bipolar disorder (N=72, n=2,615; 95% CI = 45.3–48.9). In Scottish primary care record studies, hypertension was the most commonly recorded diagnosed physical condition for schizophrenia (16%) and bipolar disorder (17.5%) although significantly less than in the control cases (Smith et al., 2013a, Smith et al., 2013b). The low prevalence identified appears to point to low rates of diagnosis.

There is an increased risk of weight gain and central (abdominal) obesity in SMI and this has been observed in untreated populations and throughout the treatment course. Weight is expressed as body mass index [BMI] = weight/height$^2$ that indicates normal, overweight and clinically obese individuals adjusted for age, gender and (ideally) ethnicity (World Health Organisation, 2013b). Meta-analyses of SMI patients from 8 studies that used the International Diabetes Federation [IDF] waist circumference criteria reported central obesity prevalence of 44.4% in schizophrenia (N= 263, 95% CI = 32.3%–56.8%) and 61.0% in bipolar disorder (N=224; 95% CI = 51.9–63.4) (Mitchell et al., 2011, Vancampfort et al., 2013b). This represents 2-2.5 times the prevalence of 23.7% in men and 26.3% in women in the UK general population (World Health Organisation, 2010).

Cholesterol is a waxy substance (fat) made by the liver and contained in some foods with a function in the manufacture of vitamin D, some hormones and bile, which is transported in the blood by specific proteins or lipids. Low-density lipoprotein [LDL] carries cholesterol from the lymph following digestion to the liver and fat cells. High-density lipoprotein [HDL] transports cholesterol from the liver for excretion in bile and faeces. Triglycerides are esters that perform the same function as LDL (transportation of dietary fat) but also transport glucose. If the ratio of LDL to HDL is too high, cholesterol is deposited in the walls of blood vessels, increasing the risk of atherosclerosis, heart disease and stroke. This same risk is associated with high triglycerides. Triglycerides are a major component of LDL although the exact relationship between them is not fully understood.. Rates for low HDL in schizophrenia have been reported as 42.6% (N = 76, n =19 280, 95% CI = 39.3%–46.0%) and, in bipolar disorder as 42.1% (N=1,861 in 17 studies; 95% CI = 40.5–43.7. The same prevalence rate was reported for hypertriglyceridemia in both disorders (39.3%) although the number of studies pooled for the schizophrenia meta-analysis was much greater (n=77:n=18) (Mitchell et al., 2011, Vancampfort et al., 2013b). In one UK cross sectional prospective screening study of 75 primary care patients with schizophrenia, significantly higher rates of dyslipidemia were identified independent of BMI and antipsychotic medication (Osborn et al., 2006).

Diabetes mellitus results from a failure of pancreatic beta-cells to compensate in insulin-resistant individuals. Insulin resistance is a vital marker of the development of DM, particularly important as treatment can be effective in the pre-diabetes phase whereas once DM has developed the only strategy is management. Glucose intolerance indicates an elevated blood glucose level that is not as high as that required for a definitive diagnosis of diabetes. The function of insulin is to allow cells to use glucose, fats and amino acids for energy. When there is high blood glucose, the body compensates by producing insulin with the opposite mechanism, maintaining homeostasis. When blood glucose is elevated over time this mechanism can become disrupted. Cells develop resistance to insulin leading to raised blood glucose (hyperglycaemia), hyperlipidaemia, hypertriglyceridemia and the development of ketone bodies. Eventually (in DM) pancreatic beta cells stop producing insulin. Prevalence of hyperglycaemia (at the same level used by NICE to indicate the need for investigation) was 19.5% (N = 47, n = 13784, 95% CI = 16.9%–22.2%) in schizophrenia and 11.4% in bipolar disorder (N=8, n=2,204; 95% CI = 9.4**–**13). Rates of DM were 10.9% in schizophrenia (N = 14, n = 2186, 95% CI 7.0%–15.5%) but prevalence was not reported in the bipolar disorder meta-analysis (Mitchell et al., 2011, Vancampfort et al., 2013b). Diabetes prevalence was significantly higher than in controls in recent Scottish primary care record studies for both schizophrenia (9% vs 5.2% p <0.001) and bipolar disorder (8.4% vs 5.3% p <0.001) (Smith et al., 2013a, Smith et al., 2013b). Diabetic ketoacidosis [DKA], a potentially fatal consequence of untreated or poorly managed diabetes, may be the first indication of DM. Just over ten times the general population incidence of DKA was reported in patients with schizophrenia prescribed atypical antipsychotics (Henderson et al., 2007).

**Nervous system disorders**

Epilepsies are a group of conditions characterised by recurrent and usually unpredictable seizures caused by either genetic or environmental factors (e.g. brain trauma). Active epilepsy has a general population prevalence of between 4-10 per 1,000 people worldwide (World Health Organisation, 2012). A significantly higher prevalence of epilepsy than in general population controls has been reported in schizophrenia, bipolar depression and (to a lower extent) in mania but causation is unclear (Leucht et al., 2007, Mazza et al., 2007).

Extrapyramidal side effects of antipsychotic medications (dystonia, dyskinesia and akathisia) are difficult to differentiate from Parkinson's disease. Dyskinesias have been shown to be prevalent in untreated schizophrenia and treatment with dopamine antagonists (antipsychotics) can lead to tardive dyskinesias (Cunningham-Owens, 1999). In the most recent primary care records studies, extrapyramidal side effects were not extracted from diagnoses read code data and this may explain the high prevalence of

‘Parkinson’s Disease’ diagnoses in schizophrenia (OR 3.07, 95% CI 2.42-3.88) and bipolar disorder (OR 3.05, 95% CI 1.83-5.09), and the narrower confidence interval in schizophrenia (Smith et al, 2013a, Smith et al, 2013b). It was the third most common recorded comorbidity in both studies.

Neuroleptic malignancy syndrome [NMS] and serotonin syndrome [SS] are rare but potentially fatal adverse effects of antipsychotic medicines, selective serotonin reuptake inhibitors and street drugs (e.g. 3,4-methylenedioxy-N-methylamfetamine [MDMA]). They increase in incidence with polypharmacy (including adjuvant lithium treatment) and dose escalation, and share similar neurological, autonomic and hyperpyrexia symptoms (Haddad and Dursun, 2008).There is also a rare and potentially fatal adverse effect of anticonvulsants with neurological symptoms (anticonvulsant sensitivity syndrome [ASS]) but this seems to have only been studied in populations with epilepsy (Knowles et al., 1999). The majority of published literature into SS, NMS and ASS consists of case reports, case-control studies and retrospective reviews, so prevalence data is not available. NMS has the most extensive literature and a recent review reported incidence had dropped from a rate of 3% to between 0.01-0.03% in the literature since 2007 (Margetic and Margetic, 2010). It appears likely that earlier recognition and intervention and improved prescribing patterns have reduced the incidence.

**Eye disorders**

Leucht et al (2007) did not find any reference to an increased prevalence of the comorbidity of eye disorders in their comprehensive literature review but a significantly increased incidence of blindness or low vision was identified in Scottish primary care register studies (OR 1.44 in schizophrenia and 1.58 in bipolar disorder) (Smith et al., 2013a, Smith et al., 2013b). A whole range of ocular adverse effects from dry eyes to retinopathy have been identified in a review of medications commonly used in SMI (Richa and Yazbek, 2010).

**Ear and Labyrinth disorders**

There is a long association between deafness and psychotic disorders and how functional disorder of the inner ear may be associated with hallucinatory and perceptual disturbance. There are no reports of increased prevalence of ear disorders from the meta-analyses in SMI, but one large epidemiological study that linked psychosis registers with army conscripts in Sweden reported a 1.8 greater prevalence of severe hearing loss in schizophrenia (David et al., 1995). A higher incidence (by a factor of 1.4 after adjustment for age) is reported in primary care schizophrenia cases in the UK (Smith et al., 2013a).

**Cardiac disorders**

CHD (also called ischaemic heart disease or congestive heart disease) is associated with atherosclerosis in the arteries and veins of the heart. This may lead to heart failure and/or angina but can be asymptomatic. Myocardial infarction (where the blood supply to the heart is interrupted) is an acute and often fatal result. Coronary heart disease [CHD] and cerebrovascular disease together make the largest contribution to mortality worldwide from CVD representing 25% of all deaths reported in 2010 (Lozano et al., 2012). Rates have been rising in the developing world and where socioeconomic deprivation limits access to healthcare, while preventative health schemes in the developed world are lowering risk (e.g. smoking cessation programmes). However in SMI in the developed world a lower than expected incidence of CVD and its risk factors (other than smoking) points to unacceptably low levels of diagnosis and treatment.

In the Smith et al (2013a, 2013b) case register studies, heart failure was no more prevalent for schizophrenia or bipolar disorder and CHD and atrial fibrillation was significantly lower than in the general population sample for schizophrenia. There was no significant difference in either for bipolar disorder. Symptoms of angina and possible myocardial infarction [MI] were investigated in a prospective, observational study of a community sample of 482 patients with schizophrenia across 6 UK sites and compared with UK health survey controls (Filik et al., 2006). There were significantly more reported angina symptoms over the last two years than in the general population sample, but no significant difference in symptoms predictive of an MI. The risk of angina remained after adjusting for age and lifestyle risk factors OR 2.17 (95% CI 1.35, 3.47). A relative risk of MI of between1.7 – 4.5 has been reported in major affective disorders but none of the studies reviewed by these authors investigated a bipolar disorder sub-group (De Hert et al., 2011).

Cardiac arrhythmia is any disorder of the heart rate or rhythm (Ames et al., 2002). It may be asymptomatic or present as dizziness, fainting and bradycardia. Although rare, it is potentially lethal as it can result in a form of ventricular tachycardia leading to sudden cardiac death [SCD] (Snowden, 2008). Potential causes include antipsychotic medication, tricyclic antidepressants, and medicine interactions (e.g. with antibiotics) (Correll et al., 2009). Inpatients with schizophrenia are reported to be three times as likely to experience SCD as individuals from the general population (Appleby et al., 2000, Ruschena et al., 1998). In a review of four studies, patients prescribed antipsychotics were reported to have higher rates of MI or ventricular arrhythmias than controls with ratios ranging from 1.7 to 5.3 (Koponen et al., 2008). There is evidence from recent research that altered autonomic function of the heart is associated with both psychopathology and metabolic profiles in schizophrenia. A negative correlation between positive symptoms and cardiac

vagal control was identified in a case control study of un-medicated acute inpatients (N=314) and a correlation between negative symptoms, metabolic parameters and heart rate variability was identified in a study by the same research team (N=94) (Chang et al., 2013, Chung et al., 2013). A known gene variant in schizophrenia has also been associated with records of 340 SCD cases in Oregon in the US (Huertas-Vazquez et al., 2013).

**Vascular disorders**

Peripheral vascular disease [PVD] usually refers to occlusion of blood vessels in the limbs due to artherosclerosis and/or embolism. Symptoms include pain, ischaemia and ulceration and can result in considerable disability and sometimes amputation. Symptomatic and asymptomatic peripheral vascular disease is a powerful independent predictor of CHD and cerebrovascular events (Golomb et al., 2006). Cerebrovascular events (stroke) can be either ischaemic or haemorrhagic. Ischaemic stroke is due to occlusion of blood vessels in the brain by an embolism or atheroma and haemorrhagic stroke occurs when the walls of the blood vessels are weakened and leak or rupture under pressure.

In the two recent case register studies in Scotland by Smith et al (2013a, 2013b) no significant difference was found between either disorder and general population controls for PVD or stroke. However, in the narrative review by De Hert et al (2011) a 1.5-2.9 fold increase of stroke in schizophrenia was reported (from 6 studies) and a 2.1-3.3 higher risk in bipolar disorder (2 studies).

**Respiratory disorders**

Respiratory symptoms were reported more often in the Filik et al (2006) prospective observational study with breathlessness, phlegm production and wheeze significantly higher in people with schizophrenia and schizoaffective disorder than in the national sample. Lung function was also significantly impaired, 41.9% had low lung function compared with only 9% in the general population sample. Chronic obstructive pulmonary disease (COPD) is progressive, strongly associated with smoking and results in considerable disability and heart failure as respiration and oxygenation becomes increasingly impaired. It effects 4.8% of the global population (Vos et al., 2012), but a significantly higher prevalence of 6% and 6.6% was identified in schizophrenia and bipolar disorder respectively, almost twice the rate in the control sample (Smith et al 2013a, 2013b). Self-reported COPD rates in SMI patients in the US are much higher (22.6%) than in control samples (Himelhoch et al., 2004).

Asthma is a common disorder of the airways, caused primarily by inflammatory processes and constriction of the smooth muscle in airway walls (bronchoconstriction). Symptoms

include wheezing, breathlessness, chest tightness and coughing. Symptoms can triggered by viral respiratory infections, exercise, smoke, cold, and allergens (e.g. pollen) and can be fatal. The lifetime prevalence of diagnosed asthma in England is estimated to be 16% in women and 13% in men (Department of Health, 2001). In studies where community patients were matched with general population samples, a significantly higher prevalence of asthma diagnosis in schizophrenia has been reported e.g. (Sokal et al., 2004, Smith et al., 2013a).

**Gastrointestinal disorders**

Dental caries and periodontal inflammation and disease is associated with diabetes mellitus, cardiovascular disease (e.g. endocarditis) and systemic infections (e.g. pneumonia) (Li et al., 2000). Poor oral and dental health is linked to many lifestyle risk factors prevalent in SMI and the planning and self-care required to optimise dental health may be impaired by cognitive and negative symptoms. Psychotropic medication may increase the risk of dental caries by increasing acidity and flow of saliva. A high incidence of poor oral health and dental status has been identified in SMI inpatients in a number of studies (Friedlander and Birch, 1990, Tang et al., 2004, Kilbourne et al., 2007, Bertaud-Gounot et al., 2013). Pain, halitosis, tooth discoloration and loss may result and contribute to poor self-esteem, stigma, and social exclusion.

Constipation can result from poor fluid intake, poor diet and low levels of physical activity. It is a common side effect of a variety of prescribed medications (such as antipsychotics and antidepressants). If left untreated, constipation can lead to bowel obstruction, intestinal ischemia, perforation and even death (De Hert et al., 2011c). Constipation is one of the symptoms of irritable bowel syndrome [IBS], a functional disorder of the gut that effects 14% of the general population (95% CI: 12-17%). IBS increases with age and lower socioeconomic status and is twice as common in women (Suares and Ford, 2011). IBS is more prevalent in major mood disorders and the most common gastrointestinal complaint in primary care (Weinryb et al., 2003). In Scottish primary care register studies, constipation was significantly more prevalent in schizophrenia (OR 3.24, 95% CI 3.00 – 3.49) and bipolar disorder (OR 3.37, 95% CI 2.93-3.88) and was the second most prevalent comorbidity after viral hepatitis for both disorders (Smith et al, 2013a, Smith et al 2013b). A diagnosis of IBS was less prevalent but still statistically significant in schizophrenia and bipolar disorder. It is worth noting that symptoms of IBS (constipation, diarrhoea and bloating) are also symptoms of withdrawal from a variety of substances (and alcohol) that may reflect comorbid substance and alcohol use or intermittent adherence to prescribed medicines.

**Hepatobiliary disorders**

HBV and HCV can be classified as infection and hepatobiliary SOCs but were discussed under infections.

**Skin and subcutaneous tissue disorders**

Psoriasis is a common autoimmune inflammatory skin disorder that can be triggered in genetically predisposed individuals by stress, infection, skin injury and certain medicines (Lowes et al., 2007). Diabetes mellitus, hypertension, cardiovascular disease and lifestyle factors have all been associated with psoriasis, as has depression (Griffiths and Barker, 2007). Exacerbation of psoriasis is one of many possible cutaneous adverse effects of lithium. An increased incidence of new presentations and exacerbation of existing psoriasis has been reported in bipolar disorder, all associated with lithium treatment (Jafferany, 2008).

**Musculoskeletal and connective tissue disorders**

Osteoporosis (OP) and osteoarthritis (OA) are two common age-related skeletal disorders. OP is characterised by low bone mineral density and fragility, leading to an increased susceptibility to fractures and OA results from cartilage loss and bone remodelling. An inverse relationship between OP and OA has been identified (Ichchou et al., 2010). Both OP and OA are thought to include genetic, environmental, metabolic and endocrine factors and are strongly associated with obesity and in women with hormone changes after the menopause (Garner et al., 2013). In the WHO Global Burden of Disease 2010 epidemiological survey the prevalence of the most commonly diagnosed OA (of the knee) was reported as 3.6% in the general population (2.6% in males and 4.7% in females), the 11$^{th}$ highest cause of disability worldwide (Vos et al., 2012). An increased prevalence was recently identified between metabolic syndrome risk factors and OA of the spine in a recent surgical sample of convenience OR 3.9 [1.4-11.6], $P < 0.01$, n=1502 (Gandhi et al., 2014).

Two reviews have identified a number of studies reporting OP or low bone mineral density in schizophrenia (Leucht et al., 2007) and in schizophrenia and major affective disorders but not bipolar disorder alone (De Hert et al., 2011). Lifestyle risk factors are undoubtedly important but there are also studies into medication adverse events that report increased prevalence of OP and fractures with hyperprolactinaemia and medicines selective for serotonin. Selective serotonin re-uptake inhibitors [SSRI] antidepressants were reported to have a dose-responsive relationship and the greatest risk of OP fractures in a meta-analysis of psychotropic medicine trials (Takkouche et al., 2007). However the small numbers of studies available for the sub-group analyses and publication bias of adverse

event data makes generalisation of these results problematic. In the Scottish primary care record studies neither OP nor OA were reported as raised in SMI populations.

**Renal and urinary disorders**

Dehydration has been reported in patients admitted to hospital with acute psychosis and there are numerous reports of polydipsia due to excessive water intoxication (rather than polyuria) in inpatient populations. One review estimated a prevalence of 5% (de Leon et al., 1994). Low fluid intake, excessive sweating or vomiting and diarrhoea and polyuria (a symptom of diabetes) may result in dehydration (Ruxton, 2012). Both dehydration and polydipsia may result in electrolyte imbalances and, if untreated, have serious cardiovascular and neurological consequences. Chronic dehydration increases the risk of urinary tract infections and kidney failure and chronic polydipsia may damage renal tube function.

The prevalence of chronic kidney disease at 7.3% was significantly higher in bipolar disorder than 2.4% in controls (OR 2.42, 95% CI 2.04-2.86) in Scottish primary care register studies, but there was no significant difference in the prevalence for schizophrenia (Smith et al, 2013a, Smith et al, 2013b). None of the schizophrenia comorbidity reviews have identified chronic kidney disease but a decrease in renal function over time in bipolar disorder is associated with lithium medication treatment. In a well conducted study of patients receiving lithium treatment versus matched control subjects with affective disorders not taking lithium, lithium patients had significantly lower glomerular filtration rates and this difference increased with increasing age and was larger in women (Tredget et al., 2010). Renal diabetes insipidus is a known side-effect of lithium treatment and at high doses, renal toxicity can occur. The incidence rate of end stage renal disease in lithium-treated patients has been estimated at 0.5% - 1.2% in those who received lithium for over 15 years (Bendz et al., 2009).

**Pregnancy, puerperium and perinatal disorders**

Obstetric complications (i.e. preterm birth, gestational diabetes, abnormal foetal growth) have been associated with schizophrenia and bipolar disorder and antipsychotic medicines (Gentile, 2010). There are known teratogenic risks with anticonvulsant medicines (particularly neural tube defects) from studies in women with epilepsy where higher doses are more frequently used (Tomson and Battino, 2009). Meta-analyses and population based studies into women exposed to antidepressants have produced discrepant results, other than adjunctive benzodiazepine use where an increase in congenital heart defects has been highlighted (Knowles et al., 1999). An incidence of 0.1% (20 times the general population rate) of the rare congenital heart valve defect Ebstein's Anomaly has been estimated for lithium, highlighting first trimester exposure as

the greatest risk (Iqbal et al., 2001). Evidence is mainly from case report registers of incidence so the data from older medicines are more available, rather than providing a robust comparison of risk. One population based cohort study using data from national health registers in Sweden compared women with treated and untreated bipolar disorder who had given birth with general population controls (n= 320, 554, 331263) (Bodén et al., 2012). If treated with antipsychotics, anticonvulsants or lithium or not, women with bipolar disorder in this study were found have an increased risk of preterm delivery, caesarean, instrumental delivery or an induction of labour (but not gestational diabetes) compared to controls. Neonates of the women with untreated bipolar disorder were at increased risk of microcephaly (small head circumference) and neonatal hypoglycaemia although both of these are features of low birth weight. Women in both bipolar groups were more likely to smoke cigarettes and use street drugs than the controls and this may have confounded the results. In addition women in the treated group may have reflected a population at the more severe end of the bipolar spectrum. As previously discussed, relapse in bipolar disorder is highly prevalent in the puerperium and increases in risk with each pregnancy. The risk of negative outcomes in women with SMI and their babies has to be carefully balanced against the risks of relapse if medications are reduced or stopped.

Psychotropic medicines not only cross the placenta, but also enter breast milk and women are advised not to breastfeed who are treated with lithium, some antipsychotics (e.g. clozapine) and benzodiazepines (Scottish Intercollegiate Guidelines Network, 2012).

**Reproductive system and breast disorders**

Antipsychotic induced hyperprolactinaemia can cause menstrual disorders (e.g. amenorrhoea), female infertility and breast disorders (e.g. galactomastia, galactorrhea), osteoporosis and sexual dysfunction (in men and women) (O'Keane, 2008, Holt and Peveler, 2011). The reported incidence of hyperprolactinaemia in people prescribed antipsychotics varies between antipsychotics and studies and may be inaccurate in studies using case records due to underreporting of symptoms and investigation by clinicians. One UK study of a wellbeing intervention tested all patients receiving antipsychotics at baseline (n=178), of which 33.1% met the diagnostic blood level criteria for hyperprolactinaemia, with a higher incidence in females than males (47.3% and 17.6%) (Bushe et al., 2008).

Sexual dysfunction can occur as an adverse effect of medicines that effect adrenergic, serotonergic and/or dopaminergic neurotransmitter systems (Taylor et al., 2012). There is a long history of sexual dysfunction in the SMI literature although a paucity of high quality research. There have been attempts to identify correlations between sexual dysfunction symptoms with specific medications and the disorder in schizophrenia. In the European First Episode Schizophrenia Trial (N= 498) subjects were tested using a sexual

dysfunction scale at baseline and at five weekly intervals throughout the trial. General psychopathology symptoms, and higher plasma prolactin levels predicted higher rates of erectile and ejaculatory dysfunctions in men. In women, higher prolactin plasma levels were identified as a predictor of amenorrhea. Negative symptoms predicted decreased libido in both men and women (Malik et al., 2011). However, reduced libido in the absence of hyperprolactinaemia has also been identified (Marques et al., 2012). Those reporting sexual dysfunction had lower quality of life scores and were significantly less likely to report having a romantic partner. Those in relationships with sexual dysfunction were more likely to rate the quality of their relationships as poor. There was no significant difference between groups in reports of ability to make friends (Olfson et al., 2005).

In epidemiological terms, 'fertility' refers to birth rate and not the ability to conceive. In an epidemiological study of the whole Danish population, the lowest first-child fertility (birth) rate was found among men (IRR=0.10) and women (IRR=0.18) with schizophrenia. In comparison, bipolar male patients had an IRR=0.32 and female patients an IRR=0.36. IRR in this study improved in both disorders and genders with increasing time from first diagnosis. Two large population based studies in Sweden and Taiwan reported the prevalence of any live birth of 0.26% and 0.06% in women with bipolar disorder compared to controls (Bodén et al., 2012, Lee and Lin, 2010).

**General disorders**

Reports of pain are common in the general population and even higher in clinical populations. Tension-type headache and migraine were the second and third highest sequelae of disease or injury in the last WHO Global Health Survey with a prevalence of 20.8% and 14.7% respectively. The leading cause of disability worldwide was low back pain (Vos et al., 2012). Pain that is non-neoplasm in origin such as musculoskeletal, neuropathic or neurogenic pain and persists despite or without treatment is associated with anxiety, depression, poor quality of life and increased risk of suicide. Comorbid pain has most frequently been studied in relationship to clinical depression where it is highly prevalent. There is much less research available into the relationship between persistent pain conditions and SMI and probably reflecting the link with depression, and more studies in bipolar disorder than schizophrenia. One very large epidemiological study examined the association between schizophrenia, bipolar disorder or depression and chronic pain in a national sample of case records of just over five million patients seen in Veterans Health Affairs facilities in the US in 2008 (Birgenheir et al., 2013). After adjusting for medical comorbidity, gender and age covariates; patients with schizophrenia (n= 93,874) compared to controls (without schizophrenia, bipolar disorder or depression) were significantly less likely to have any recorded pain condition (OR=0.91). When different types of pain were compared the schizophrenia subjects had significantly higher chronic

(OR=2.10), migraine (OR=1.13), other headache (OR=1.46) or psychogenic (OR=2.72) pain. In the bipolar disorder adjusted sample (n= 96,186) there were significantly higher recorded diagnoses of any pain condition (OR=1.83), as well as every specific pain condition (adjusted ORs ranged from 1.50 to 6.24). It was interesting that a significant odds ratio for arthritic and neuropathic pain was only present in the schizophrenia sample before adjustment for comorbidity and age covariates. This suggests an under reported and/or clinically identified level of chronic pain in this population.

## Chapter Summary

In serious mental illness, a higher than expected prevalence of physical comorbidities has been identified in every system organ class except the blood and lymphatic system. There is considerable overlap between the physical comorbidities identified as important in SMI that points to genetic vulnerability, environmental risk factors and social/behavioural factors. A lower than expected incidence or absence of many conditions in primary care records highlights poor identification of physical comorbidity in this population.

# Chapter Three: Mortality

## Early mortality in SMI

In 2013 information linking data on adults who use secondary mental health services in England with mortality data from the Office of National Statistics was published for the first time (Health and Social Care Information Centre, 2013). In the year examined (2011-2012), the mortality rate [MR] in people who had received at least one episode of mental health care was 3.6 times that expected in the general population. This represented 83,393 deaths over the year (5.2% of patients). The cause of death that made the largest difference was dementia. However, the largest difference by age was in mental health service users in their 30's where the rate was nearly five times above the general population. In service users under 74 years the main causes of death were ischaemic heart disease (9.9%) and liver disease (7.6%). Primary diagnosis was not captured in this analysis.

In the WHO Global Burden of Disease study the contribution of Years of Life Lost [YLLs] to the calculation of Disability Adjusted Life Years [DALYs] in mental health and substance use disorders was small (Whiteford et al., 2013). Mortality data was largely taken from national death registers that rarely reflect mental health or substance use disorder as the primary cause of death. If a person dies as a result of an MI, for example, ischaemic heart disease will be recorded and not schizophrenia. Suicide is classified in ICD-10 in the 'injuries' class. The mental health and substance use disorders group recalculated DALYs by adding estimates for suicide into their data model. This resulted in a substantial increase in the disease burden ranking for mental and substance use disorder, from 6$^{th}$ to the 3$^{rd}$ worldwide (Whiteford, 2013).

Mortality can be calculated and presented in different ways and methods are not directly comparable. Standard mortality ratio [SMR], mortality rate [MR], Mortality Rate Ratio [MRR], risk ratio [RR], years of life lost [YLL] or life expectancy may be used. SMR reflects the number of observed deaths divided by the number of expected deaths in a population in the period studied.

There have been three meta-analyses that have calculated SMR estimates in SMI. Harris and Barraclough (1998) calculated separate SMRs for schizophrenia and bipolar disorder from papers published between 1966 and 1995 (20 studies and 6 studies). Two meta-analyses focused on schizophrenia alone (Brown, 1997, Saha et al., 2007). The most

recent of these used robust reporting and analysis guidelines and international data from the largest number of studies (37, n=22 296 patient deaths) (Saha et al., 2007). The earlier analyses reported all cause SMRs of between 1.48-1.6 in schizophrenia (Brown, 1997, Harris and Barraclough, 1998). Saha et al (2007) reported a median all-cause mortality of 2.58, with 10% and 90% quantiles ranging from 1.18-5.76. There was no difference in SMR distributions by gender. In bipolar disorder, a slightly lower all-cause SMR of 2.02 (1.88-2.17) was estimated (6 studies, n= 4547 deaths) (Harris and Barraclough, 1998). A systematic review of 17 studies of 331,000 patients with bipolar spectrum disorders (that included schizoaffective disorder) reported a 2-3.5 higher mortality risk (Roshanaei-Moghaddam and Katon, 2009).

Two case record linkage studies have examined cohorts of patients of UK secondary mental health services in Southampton (schizophrenia n=370) and London (schizophrenia n=7022, schizoaffective disorders n=1313 and bipolar disorder n=2700) (Brown et al., 2010, Chang et al., 2010). In schizophrenia and bipolar disorder, SMR was broadly similar to that of Saha et al. The reported SMR for schizoaffective disorder was 2.52 (95% CI 1.83-3.39). Although based on a relatively small number of deaths (n=44) this could represent a greater severity of illness and/or exposure to risk. In the 25-year follow-up study gender difference was non-significant despite an earlier mean age of death in men (Brown, 1997). In the 2 year follow-up study, a statistically significant association between higher all cause SMR and female gender for schizoaffective and bipolar disorder was identified (Chang et al., 2010).

Both Brown (1997) and Saha et al (2007) identified a trend of increasing SMRs in schizophrenia compared to the general population since 1970. This is unlikely to mean that improvements in life expectancy in schizophrenia are failing to keep pace with those of the general population, but reflect a real and significant fall in life expectancy over time. There are many factors that may contribute to early mortality in SMI and could separately or cumulatively contribute to the growing SMR gap. These will first be considered under unnatural and natural causes of death before health behaviour risks and system factors are discussed in the next chapter.

**Unnatural causes of mortality**

In the UK doctors are required by law to report deaths to the coroner where they believe the cause is ‘unnatural’, where the death is sudden, the cause is unknown, there has been violence, the death occurred in custody or they suspect an industrial cause[1].

[1] Section 8(1) Coroners Act 1988

Reporting of deaths in hospital or immediately post discharge is governed by local guidelines.

With up to 80% of all deaths in mental health and substance use disorders attributable to suicide where suicide is studied as the primary outcome (Harris and Barraclough, 1997, Yoshimasu et al., 2008), it is not surprising that unnatural causes make up the largest proportion of mortality in SMI studies. In the Saha et al (2007) meta-analysis 7 studies contributed to the calculation of unnatural cause SMR in schizophrenia providing a median SMR of 7.40 (10% and 90% quantiles 5.56,12.73). People with schizophrenia were over 12 times more likely to die from suicide than those in the general population (median SMR 12.86). The SMR for accidents was less but still above the general population rate (Median SMR 1.73).

In bipolar disorder Harris and Barraclough (1998) report an unnatural cause SMR of 9.18 (95% CI 8.01-10.46) and a suicide SMR of 15.05 (95% CI 12.25-18.44). The highest suicide SMR was in the 'affective disorders not otherwise specified' diagnosis category (19.85 CI 17.14-22.86). The SMR for accidents was not reported but 'other violent means' were just over three times that of the general population (3.17 95% CI 1.17-6.91).

Accidental death in SMI was investigated in a large cohort study of all adults in Sweden in 2001 who were followed-up for 8 years (Crump et al., 2013). Accidental death was 2-4 times above that of the general population and more prevalent in men. Women with bipolar disorder were most likely to die as a result of a fall and men with schizophrenia by accidental poisoning. After adjustment for comorbid alcohol and substance use disorders, accidental death risk remained over twice that of the general population, except in men with bipolar disorder (RR 1.63 95% CI 1.29–2.12).

Reports of unnatural cause SMRs are all likely to be underestimates, particularly for women. An analysis of the proportion of reporting rates of unnatural deaths to coroners across all jurisdictions in England and Wales between 2001 and 2010 demonstrated a large variation, with women's deaths much less likely to be reported or determined 'unnatural' at an inquest (Mclean et al., 2013). Many deaths fall in the "grey" area between those that are clearly natural and those that are unnatural, and there are no guidelines to help doctors when certifying such cases (Roberts et al., 2000). Common examples include deaths after surgery or medical intervention, where there has been a disease process and trauma, or death as a result of infection. For example pneumonia from aspiration following intoxication or resulting from a fall and/or osteoporotic fracture may be recorded as a natural (respiratory system) death.

**Natural causes of mortality**

As was discussed earlier, there is evidence for increased prevalence rates of physical comorbidities in all the system organ classes of the body in SMI apart from blood and lymphatic disorders.

**Table 3:1 Natural mortality rates in SMI**

| | **Schizophrenia** | **Affective disorder not otherwise specified** | **Bipolar** |
|---|---|---|---|
| All natural causes | SMR 2.31 (SD 1.18) (Saha 2007) | | MRR: males 5.61 (95% CI 4.56, 6.90): females 3.73 (95% CI 3.03, 4.56) (Laursen et al., 2011) |
| Cardiovascular | SMR 2.01 (SD 0.83) (Saha et al, 2007)<br>SMR 2.25; 33% of deaths (Brown et al, 2010) | SMR 1.60 (95%CI 1.30-1.94) (Harris and Barraclough, 1998) | SMR 1.58 (95%CI 1.39-2.34) (Harris and Barraclough, 1998)<br>SMR 2.00 (Laursen et al., 2013) |
| Cancer | SMR 1.44 (SD 0.6) (Saha et al, 2007)<br>SMR 1.49 (Brown et al, 2010) | | |
| Respiratory | 19% of deaths (Brown et al, 2010) | | Unclear |

Table 3.3 summarises the data for the natural causes of death in these populations. Cardiovascular causes of death are the most common. Brown et al (2010) also demonstrated a trend in an increasing numbers of cardiovascular deaths over the 25 years studied that approached significance ($P$ = 0.053). A highly significant fall in suicide rates was identified over the same time period ($P$ = 0.0002), suggesting it is cardiovascular disease that is making the greatest contribution to the widening SMR gap. The SMR data for respiratory disease as a cause of death in bipolar populations is less reliable in this analysis as it was estimated from only one study per subgroup with small numbers of deaths in each (n=3, n=12). Both studies were from inpatient populations where respiratory disease is more prevalent (Harris and Barraclough, 1998).

In the USA a range of 13.5-32.2 potential years of life lost [YLL] due to early mortality compared to the general population for patients of public mental health services has been reported (Colton and Manderscheid, 2006). A broad range of diagnoses including major depressive disorder were included and the data from the eight states involved was not combined because it covered different time frames and types of service. In Scandinavia YLL in schizophrenia and bipolar disorder is estimated to be 11 to 20 years for men and 11 to 17 years for women, with a slightly better prognosis in bipolar disorder and a worse prognosis in men with schizophrenia (Laursen et al., 2013). In the UK there have been similar findings with the shortest life expectancy reported in women with schizoaffective disorder (17.5 YLL) and men with schizophrenia (14.6 YLL) (Chang et al., 2011).

## Chapter Summary

A two-three times greater mortality in schizophrenia than in the general population and slightly lower (around twice the general population mortality) in bipolar disorder is estimated in the most recent cohort studies and meta-analyses (Saha et al., 2007, Brown, 1997, Chang et al., 2010, Laursen et al., 2011). There is a paucity of mortality data specific to schizoaffective disorder. The highest rates of mortality are reported in younger men with schizophrenia and women with bipolar and schizoaffective disorder. This may be a feature of the course of illness and treatment, or represent a gender bias towards an affective diagnosis in women. Suicide makes a significant contribution to early mortality but rates have been generally falling since the 1980's. In contrast a widening mortality gap in the same time frame for all-cause mortality points to an increase in natural causes, specifically cardiovascular disease. Unnatural causes of death are likely to be under reported and registered and this impacts considerably on the estimates made for the disease burden of all three disorders.

# Chapter Four: Risk factors

## Why do people with SMI die early?

There are multiple risk factors that contribute to early death in SMI and all are potentially modifiable and present targets for intervention.

### Symptoms and illness course

A study that measured external locus of control found patients with SMI significantly more likely to believe their physical health is determined by powerful others and chance than those with non-psychotic disorders (Buhagiar et al., 2011). Hallucinations and delusions may theoretically increase risk by inferring protection, making people avoid or take certain actions or by distracting attention. Over-activity, hostility and impulsive behaviour may increase risk and all symptoms may result in a failure to attend to adequate self-care. Cognitive deficits and negative symptoms may reduce recognition of physical symptoms or help seeking behaviour (Jeste et al., 1996). A lower pain threshold is reported in schizophrenia, although it is not known if this is intrinsic to the disorder or related to analgesic effects of medication (Jarcho et al., 2012). Impaired dopaminergic reward pathways in the brain may result in compulsive behaviour and craving leading to increased risk taking and/or addiction (Comings and Blum, 2000). People with schizophrenia living in the community are less likely to perform self-care or health promotion activities than non-psychiatric samples (Lieberman and Test, 1987, Holmberg and Kane, 1999). Apathy that is distinct from depression can impact on engagement with health professionals, treatment or behaviour change (Yazbek et al., 2013).

A study of 6,880 SMI patients linked mortality data with one retrospective clinical rating of symptom severity from case records per patient (Hayes et al., 2012). A second cohort study followed-up 300 patients with schizophrenia for 8.5 years using baseline symptom ratings (Loas et al., 2011). No significant association between positive symptoms or hostility and mortality was identified in either study. In the second study subjective ratings of symptom severity at baseline was significantly positively correlated with suicide mortality. There is evidence from a recent study that severity of positive symptoms in schizophrenia impacts negatively on cardiovascular recovery from exercise (Ostermann et al., 2013). This could be relevant to the aetiology of arrhythmias and sudden cardiac death [SCD]. A cross sectional study that used physical fitness as a proxy for CVD risk found a positive correlation between the severity of depressive, negative and cognitive symptoms in schizophrenia and low performance (Vancampfort et al., 2013a). Length of illness, smoking and self-rated inactivity at baseline were features of these patients compared to healthy controls.

Evidence on the impact of affective symptoms is mainly from unipolar depression where there is considerable evidence of increased all cause and CVD mortality risk (Cuijpers and Smit, 2002, Hare et al., 2013). One large US study investigated a general population cohort so is more likely to have been more representative of a bipolar population than studies utilising psychiatric registers (Ramsey et al., 2013). Participants were screened for mania at baseline and followed-up for 26 years. Subjects reporting at least one manic spectrum episode at baseline had significantly higher all cause mortality between 34-64 years. Mortality risk was independent of depression and was not associated with hypomania alone. There was no investigation of the causes of death or adjustment for health behaviours.

**Sleep disruption and disorder**

Sleep of an adequate duration and quality is important for physical and mental health. Sleep is a complex process that enables the brain to recover, reorganise and regenerate (Mental Health Foundation, 2011). Shorter and longer sleep duration were associated with an increased risk of all cause mortality in the general population in a meta-analysis of 27 studies (Cappuccio et al., 2010b). A recent meta-analysis found a significant association between sleep disturbance and an increased relative risk for suicidal ideation, attempt and completion (Pigeon et al., 2012). An important finding by these authors was that these risks were independent of depression.

Insomnia is associated with fatigue, daytime sleepiness, poor concentration, irritability, memory loss, poor function, depression and a weakened immune system (Roth, 2007, Imeri and Opp, 2009). Insomnia and oversleeping are associated with the development of diabetes and CVD (Cappuccio et al., 2010a). A sleep-wake cycle that is synchronised with the environment (circadian rhythm) is important. Female night-shift workers have higher incident rates of breast cancer and a higher incidence of metabolic syndrome and CVD is observed in occupations that work at night (Megdal et al., 2005, Esquirol et al., 2011). Hypersomnia (a severe form of daytime sleepiness) may indicate the potentially serious respiratory condition, obstructive sleep apnea [OSA]. OSA is more common in obesity, post-menopausal women, smokers and users of alcohol and (untreated) is associated with hypertension, CVD, stroke, accidents and poor quality of life (Young et al., 2002).

Originally thought to be a symptom of mental disorder, the causality of sleep dysfunction is now thought to be bidirectional (Krystal, 2012). Sleep problems commonly predate the diagnosis of schizophrenia and bipolar spectrum disorders (Spiegelhalder et al., 2013, Plante and Winkelman, 2008). A decreased need for sleep is part of the diagnostic criteria for mania and occurs just before a switch from depressed mood to hypomania and/or mania (Wehr et al., 1982). Circadian rhythm disorder is present in bipolar disorder and schizophrenia and disturbances of sleep architecture in schizophrenia (Gonzalez, 2014,

Wilson and Argyropoulos, 2012). Insomnia is associated with schizophrenia, unipolar and bipolar depression (Krystal, 2012). Some psychotropic medications improve sleep duration and quality but can lead to daytime sleepiness and others (and most substances of abuse) impair sleep. Objective or subjective improvements in sleep are early signs of recovery (Spiegelhalder et al., 2013).

**Physical and psychological stress**

Physical and psychological stress is a state where homeostasis is threatened or there is a perception of threat (Chrousos and Gold, 1992). Stress is mediated through the hypothalamic–pituitary–adrenal [HPA] axis and the sympathetic nervous system [SNS] to impact on the body, brain and behaviour (Bradley and Dinan, 2010). A dysfunctional response to acute or chronic stress may lead to the development of inflammatory, metabolic and cardiovascular disorders (McEwen, 2006). For example, a failure to deactivate the stress response can lead to over exposure to cortisol and result in metabolic syndrome [MeTS] (Rosmond, 2005). An extensive systematic review of all studies investigating HPA function in schizophrenia found evidence that over exposure to cortisol in schizophrenia predicted MeTS and cardiovascular disease mortality (Bradley and Dinan, 2010). High and low levels of cortisol were predictive of suicide. Studies in early intervention samples and of drug naive patients were equivocal but dysfunctions in the stress response were found across the illness course.

**Risk taking, suicide and accidental death**

Impulsivity and risk taking behaviour are increased in SMI, contribute to accidental death and suicide and are more prevalent when alcohol or substance use is present (Swann et al., 2005, Swann, 2009, Zhornitsky et al., 2012). Prescribed medications may contribute to risk through common side-effects (e.g. sedation), intentional or unintentional overdose (Reddy et al., 2014). Medication treatment is also important to the reduction of risk. Lithium treatment significantly reduces suicide rates and clozapine reduces suicidal intent (Cipriani et al., 2013, Meltzer et al., 2003). The highest suicide rates of all in SMI are reported in first episode schizophrenia patients who do not adhere to prescribed medication (Tiihonen et al., 2006).

**Health behaviour.**

*Smoking*

Smoking behaviour is the largest modifiable risk factor for cardiovascular disease worldwide. The significant reduction in smoking seen in the general population in the developed world in recent years is not matched in SMI. Smoking rates of around 50% in SMI, twice that of the general population, are reported in the most recent meta-analyses (Vancampfort et al., 2013b, Mitchell et al., 2011). A study that investigated smoking

behaviour in patients enrolled in a variety of studies from 1999-2011 found higher rates of smoking in schizophrenia (64%) than bipolar disorder (44%) with heavier and longer smoking histories in the schizophrenia samples (Dickerson et al., 2013).

Like all health behaviours, nicotine dependence and smoking behaviour cannot be divorced from psychopathology or other risk behaviours. In schizophrenia studies have shown an association between increased smoking behaviour, higher symptom scores and abuse of substances (Bobes et al., 2010). Activation of nicotinic acetylcholine receptors is demonstrated to enhance selective attention so may improve symptoms or functioning (Dervaux and Laqueille, 2008). Hydrocarbons in cigarette smoke have a direct pharmacokinetic effect on the liver metabolism of several psychotropic medicines, reducing effectiveness and side-effect burden (Kroon, 2007).

*Alcohol and substance use*

Alcohol and substance use disorders are highly prevalent in SMI, contribute to a worse prognosis and considerable mortality, including suicide (Swofford et al., 2000). A lifetime prevalence of around 50% has been estimated in systematic reviews of schizophrenia studies in North America (Selzer and Lieberman, 1993 ). A German study using a drug and alcohol questionnaire and biochemical screening estimated a lifetime prevalence of 21.8-42.9% with the highest rates in male long stay patients (Soyka et al., 1993). Short-term (2-3 month) estimated prevalence was also high (21.3-23.9%), with alcohol the most common substance of abuse. A cohort study that interviewed 1,208 patients from nine centres across Europe reported highest lifetime prevalence rates in the UK (35%) (Carrà et al., 2012). Choice of substance may be linked to availability, rather than preference (Verdoux et al., 1996). Cannabis is the street drug with the highest prevalence and has been associated with the development of schizophrenia, particularly use at an early age (Smith and Hucker, 1994, Zammit et al., 2002, Jablensky et al., 1992). Cannabis is reported to have negative and positive effects on psychotic symptoms and may ameliorate some side effects of psychotropic medication (Dixon et al., 1990). Cannabis is commonly smoked with tobacco making the exact mechanism of these effects difficult to determine.

*Caffeine*

Excessive caffeine consumption is reported in SMI and associated with insomnia and hostile/aggressive behaviour, particularly in acute settings (Simmons, 1996). Pharmacokinetic interactions between a range of psychotropic medicines and caffeine reduce their effects. Restriction of caffeine may have unintended consequences and withdrawal can increase agitated behaviour. High doses of caffeine are readily available from the diet but also from popular ‘high energy’ drinks, often consumed with alcohol. Caffeine can enable a greater consumption of alcohol over longer periods of time by

reducing the sedative effect (Arria et al., 2011). Risk-taking behaviour increases because the person overestimates their ability to function (Marczinski et al.). Additive effects in the dopamine reward system may increase the risk of addiction. A significant association between daily caffeine intake rate and cigarette smoking rate has been observed in schizophrenia compared to controls (Adolfo et al., 2009).

*Diet and fluid intake*

Problems accessing, affording, cooking or understanding a healthy diet are all cited as barriers to eating healthily in surveys of the general population in England (National Obesity Observatory, 2011). People reporting existing health problems were more likely report obesity and lower confidence in changing their current behaviour. Studies in schizophrenia report a much higher than recommended intake of sugar, salt, carbohydrate and fat and low intake of fruit, green vegetables and fibre (Scott and Happell, 2011, Dipasquale et al., 2013). Poor nutritional content, a lack of variety, overreliance on convenience foods and poor diet literacy is identified in studies using food diaries (Henderson et al., 2006, Hardy and Gray, 2012). Low fruit and vegetable intake, high consumption of carbohydrate and sugary 'snacks' or drinks and a higher incidence of binge eating is reported in bipolar disorder (Sylvia et al., 2013a, Elmslie et al., 2001, Kruger et al., 1996, Ramacciotti et al., 2005). There has been a recent focus on malnutrition in care environments associated with the elderly but the quality of nutrition in residential or supportive environments for adults with SMI has received little attention. Despite nurses reporting knowledge of an association between poor nutrition and psychotic disorders, 29% of patients who screened positive for malnutrition in one small study had not previously been identified (Abayomi and Hackett, 2004). Fluid intake may be impaired (or polydipsia may be present) in SMI leading to dehydration and electrolyte imbalance as discussed previously.

*Physical activity*

Physical activity and exercise has the potential to improve mood, symptoms, physical health and health related quality of life in SMI (Faulkner and Carless, 2006). Low levels of physical activity are reported in schizophrenia and are associated with negative symptoms and the sedative effects of medication (Brown and Birtwistle, 1999, Goff et al., 2005). There is limited evidence that exercise improves negative symptoms and physical fitness in this population (Gorczynski and Faulkner, 2010). Although there is robust evidence for the benefits of exercise in depressive disorders, there has been much less attention to physical activity in bipolar disorder. One European study surveyed 482 participants with bipolar disorder about their experience of exercise over the preceding year and reported an association between mood and reported activity levels (Sylvia et al., 2013b). No significant differences in physical health parameters at baseline, other than BMI (that was

higher in participants screening positively for depression) was found. The cross sectional design limits the interpretation of these results.

*Medication non-adherence*

Medication non-adherence is very common in all long-term conditions, including SMI. Non-adherence predicts suicide risk and would be expected to influence all the other risk factors in this chapter. Adherence in SMI has been defined as taking 80% or more of prescribed medication and partial non-adherence between 50 and 80% (Velligan et al., 2009). Stopping and starting medication, particularly when unsupervised, risks withdrawal effects, relapse and adverse effects of titration. For example rebound insomnia may increase risk-taking behaviour, sedation and hypotensive effects may increase the risk of accidents. A meta-analysis in schizophrenia reported a relative risk of suicide of 4.2 (95% CI 1.7–10.1) in non-adherent compared to adherent patients (Leucht and Heres, 2006). Other than suicide, no independently sponsored reviews could be identified that specifically investigate the impact of non-adherence on mortality outcomes in SMI. Two out of three reviews into the consequences of partial non-adherence conclude with recommendations for the long acting injections promoted by the funder (Llorca, 2008, Higashi et al., 2013, Keith and Kane, 2003).

**Iatrogenic risks**

An iatrogenic risk is defined by the online Oxford English Dictionary as one ‘induced unintentionally by a physician through his diagnosis, manner, or treatment’ (Oxford English Dictionary, 2014). This definition has not changed since the first entry in the dictionary in 1924 although treatment and care is no longer totally led by the medical profession. Organisation and delivery of care by many professional groups and workers can significantly impact on patient safety and is included in this section.

A meta-analysis of case record review studies of iatrogenic risk events in adult non-psychiatric in-patients calculated a median incidence of 9.2% (IQR 4.6–12.4%) events across 74,485 patient records from 8 studies (de Vries et al., 2008). Many events (44%) were judged preventable and 7% resulted in death. The most common causes were related to surgery (40%) or medication (15%). System related factors accounted for around 8% of events in the 5 studies where this was investigated (n=2,324 records). There has been a surprising lack of good quality research into iatrogenic risk events in psychiatric populations. The majority of studies that do exist focus on the analysis of incident and accident reports from inpatient samples of convenience. In the UK these highlight the risk of falls and the consequences of the environment and management strategies for self-harm, aggression or suicide e.g. (Fairlie and Brown, 1994, Bowers et al., 2007).

*Medication risk*

Many medication-related comorbidity risks were discussed in the comorbidity chapter. For example, falls may be more common where there is sedation and more fatal where there is comorbid disease. Safe prescribing and medicines management practice could presumably moderate these risks.

Medication errors include those associated with prescribing, transcription, dispensing, administration, monitoring and information exchange (National Reporting and Learning Centre, 2014). Incidence rates of medication errors in psychiatry vary considerably between studies, are largely of inpatient populations and are too heterogeneous to allow meta-analysis (Maidment et al., 2008, Procyshyn et al., 2010). In one survey of 22,036 prescription items written in one week in mental health units across 9 NHS Trusts pharmacists identified 2.4% (n=523) prescribing errors (Stubbs et al., 2006). Of these, 22 (4.3%) were judged likely to result in serious adverse effects or death. Non-psychotropic prescribing has been reported to generate more errors than psychotropic prescribing in these settings, indicating increased risk where there is physical comorbidity (Haw et al., 2007b, Rothschild et al., 2007). There are, as yet, no studies into prescribing errors by non-medical prescribers in the UK.

The administration of medication is by registered nurses in the UK, although this role can include the supervision of students and self-administration by patients in hospital and community settings (Nursing and Midwifery Council, 2007). Medication administration errors are a deviation from a valid prescription, standard or policy, including failing to correctly record the administration or reason for omitting medication. A retrospective analysis of incident reports over a period of 3.5 years in one UK psychiatric hospital identified 104 administration errors. Psychotropic, long-acting intramuscular antipsychotics and as-needed medicines were all significantly overrepresented. 14% of errors had the potential to cause moderate harm to patients and 1% could have led to severe harm (Haw et al., 2005). As this study was based on reports it is likely to have grossly underestimated the scale of the problem due to anxiety about disciplinary action. An observational study on two wards in the same hospital detected 369 errors in 1,423 administration items (25.9%). There were no incident reports in the same time period. The design meant there was an opportunity to intervene to prevent risk and only one error was rated as having the potential to cause serious effects (Haw et al., 2007a). Similar to prescribing errors, administration errors were significantly more likely to involve non-psychotropic than psychotropic medicines.

The largest amount of information on iatrogenic risk of medication is from reviews of adverse event data from clinical trials funded by the pharmaceutical industry and this is subject to publication bias. A study of 162 randomized, double-blind, placebo-controlled

trials published in peer reviewed psychiatric journals between 2001 and 2003 found authors were 4.9 times more likely to report positive results if one of them declared a conflict of interest and the study was industry sponsored (Perlis et al., 2005).

When considering mortality risks, the impact of medication on the risk factors with the greatest impact on mortality (suicidality and metabolic syndrome) are arguably the most important. With respect to suicide some psychotropic medication can be fatal in overdose, others have efficacy against suicidality and/or are proven to significantly reduce the suicide rate as previously discussed. The impact of antipsychotic medications on the risk of metabolic syndrome is highly controversial, with conflicting results from studies and reviews. There is evidence of elevated risk linked to weight gain (particularly for olanzapine and clozapine), largely from industry trial data (Newcomer, 2005, De Hert et al., 2012). In clinical populations the association is less clear because the majority of patients have had long exposure to a variety of medications, do not always adhere to treatment and have multiple risk factors. In studies where subjects are antipsychotic naive at baseline, the greatest risk of weight gain and metabolic abnormalities is reported in the first few weeks of treatment (Tarricone et al., 2010). However, these results may be confounded by short duration of follow-up (≤3 months) and the use of lower risk antipsychotics where subjects have existing metabolic abnormalities or familial risk factors.

Long-term exposure to any antipsychotic treatment was significantly associated with lower mortality than no drug use in an important independently funded cohort study in schizophrenia, with clozapine posing the lowest risk (Tiihonen et al., 2009). This study followed up 66,881 patients for 11 years so represented survivors at each census point. Causality for death was not investigated but it is possible that patients who survived the longest were more adherent and/or that medication had more successfully targeted risk factors such as psychopathology, sleep dysfunction, substance use or suicidality. Supporting this argument is the relative success of clozapine in this study and it's known action and/or proven efficacy against each of these important factors (Essali et al., 2009, Asenjo Lobos et al., 2010, Armitage et al., 2004, Brunette et al., 2006, Meltzer et al., 2003). Alternatively long-term antipsychotic exposure could be an indication (a proxy measure for) of engagement with health care.

*Systems risk*

The risk to individual patients extends beyond actions or omissions by individuals or specific professional groups to how care is organised and risk factors within or as a result of this system. There is a culture of risk assessment in SMI in mental health services in the UK that focuses on the risk of suicide or potential harm due to violence or vulnerability to exploitation. Risk assessment tools currently used in UK mental health services only include items on the potential risk (of self-harm) or any difficulty accepting or managing a

known physical health problem, for example, the widely used Sainsbury's Risk Assessment Tool (Morgan, 2000). A new guide to risk assessment and management designed for mental health professionals does not include any assessment of previously unknown physical health risk (Hart, 2014).

The requirement for mental health nursing students to achieve competence in physical health skills at the point of registration in the UK was implemented into undergraduate curricula from 2011 (Nursing and Midwifery Council, 2010a, Nursing and Midwifery Council, 2010b). Surveys of mental health nurses [MHNs] and Care-Coordinators in the existing workforce report a positive attitude towards a physical health care role but highlight a number of barriers to carrying this out in practice (Hyland et al., 2003, Nash, 2005, Howard and Gamble, 2011, Nash, 2010, Robson and Haddad, 2012). Barriers include workload, time, other priorities, a lack of resources, education and equipment and problems sharing information between providers across service interfaces. One small study (of 37 MHNs in acute inpatient units in one NHS Trust) included an audit of the patient record and found low levels of documented physical health assessment or interventions (Howard and Gamble, 2011). Confusion is often expressed about whose role it is to provide physical care. Some mental health nurses in these studies expressed the view that 'we don't do physical health' and 'it is the role of the GP'. In the study by Hyland et al (2003), case managers were largely pessimistic about their ability to change the health behaviours of patients with SMI. All studies so far have been into convenience samples and subject to response bias so how widely these views are shared is not known.

Cross sectional surveys have demonstrated that people with SMI attend primary care more frequently than the general population, have longer consultation times and contact with primary care represents about two thirds of all health contacts (Nazareth and King, 1992, Burns and Cohen, 1998, Kendrick et al., 1994, Kai et al., 2000, Reilly et al., 2012). Until 2014, GPs in England were paid to provide annual CVD screening to people with SMI registered with their practices through the Quality and Outcomes Framework (British Medical Association and NHS Employers, 2012 ). Studies have demonstrated that this screening does not routinely take place and, where it does, is less frequent and less comprehensive than the CVD screening provided to people with other long term conditions (Mitchell and Hardy, 2013, Hardy et al., 2013, Roberts et al., 2007). Surveys of GPs and practice nurses report that many feel ill equipped to provide care for people with SMI and some believe it is beyond their remit (Bindman et al., 1997, Lester et al., 2005). The incentive for cardio-metabolic testing in SMI in primary care (other than for blood pressure) was removed from the GP contract in 2014 (British Medical Association and NHS_Employers., 2014). Physical health monitoring and intervention must now be provided or coordinated from secondary (mental health) services for the first year following admission (National Collaborating Centre for Mental Health, 2014)

Multi-disciplinary Community Mental Health Teams [CMHTs] have provided mental health care in the UK since the 1980's. There are specialist CMHTs (e.g. assertive outreach teams) and generic CMHTs. CMHTs usually include psychiatrists, mental health nurses, social workers, occupational therapists and support workers. Core functions of CMHTs are defined locally and include case management and coordination of care for people with SMI between primary care, secondary mental health services and social care. Guidance issued from the Department of Health [DOH] emphasizes the importance of joint working with primary care to achieve optimal physical health care for people with SMI (Department of Health, 2002). Joint working is also known as 'collaborative care' and is recognised as a complex intervention (Butler et al., 2008). Problems have been identified in the ability of CMHTs to effectively perform this function for people with SMI due to high caseloads, low contact time and problems with interface communication (Sainsbury Centre for Mental Health, 1998, Crawford et al., 2004, Freeman, 2002). A recent systematic review of collaborative care approaches for people with SMI failed to find any evidence of effectiveness for collaborative care over standard care for physical health related quality of life (Reilly et al., 2013). Research into specialist CMHTs is limited. Assertive outreach teams are more effective at engaging patients than generic CMHTs, but no more effective in preventing rehospitalisation (Killaspy et al., 2006). An upward trend in suicide rates has been observed in UK NHS Trusts where specialist community teams have merged into generic teams, prompting guidance to preserve assertive outreach and early intervention services (National Confidential Inquiry into Suicide and Homicide by People with Mental Illness). In times of austerity, commissioners may focus on short-term expensive outcomes such as preventing hospitalisation rather than health promotion and harm minimisation that can take a considerable time to result in measurable change.

In England, integrated CMHTs that include health and social care staff in one team are now being formed based on clustering of patients by need to enable a 'payment by results' currency system to operate between commissioners and providers of services (Department of Health, 2013). The effectiveness of this approach for people with SMI has not been tested, although a mismatch between ICD-10 diagnosis and allocation to the correct cluster has been identified, particularly for psychotic disorders (Bekas and Michev, 2013). An increase in the suicide rates of patients of organisations where integrated teams have replaced specialist community teams has been highlighted (While et al., 2012).

**Stigma and social exclusion**

People with SMI are identified as being amongst the most excluded groups in society (Social Exclusion Unit, 2004). Stigma is a social construction that devalues or dehumanises people as a result of a distinguishing characteristic or label (Lauber).

Discrimination and stigma increase the likelihood of unemployment, poverty, social isolation and poor housing. These factors not only contribute to disease and mortality risk but interact with each other. For example, poverty may lead to inadequate nutrition and, along with poor transport links, reduce access to health care to treat the results. Even where there is contact with services and health professionals, being identified as 'mentally ill' may mean a failure to treat the whole person (Schulze, 2007). Symptoms and risk factors may be overlooked in a process known as 'diagnostic overshadowing' (Jones et al., 2008). Self-stigma may reduce help seeking behaviour and/or the confidence to make positive changes to health behaviours (Watson et al., 2007). Low expectations from staff or 'therapeutic pessimism' may result in a culture of less engagement, investment of resources and intervention (Thornicroft et al., 2007, Horsfall et al., 2010). People with SMI may find it difficult to navigate the fragmentation of health services, i.e. separation of psychiatric and medical services. Carers of people with SMI and the staff who work with them may themselves face negative attitudes that impact on collaborative care.

### The consequences of multiple risk factors

The distribution of risk in individuals differs from what would be predicted from individual risk factor prevalence alone. Major risk factors tend to cluster together in individuals, as in metabolic syndrome. Risk factors interact with each other to multiply an individual's risk of developing comorbid disease over time. This is recognised in the prediction of the risk of cerebral and cardiovascular disease (Anderson et al., 1991, Chang et al., 2001, Jackson et al., 2005). As a consequence, a number of multivariate risk prediction models have been developed to allow calculation of the future likelihood of cardiovascular disease in the general population, for example, the Framingham risk score (D'Agostino et al., 2008) and the QRISK (Hippisley-Cox et al., 2008). In SMI the main focus of risk prediction research has been violence and suicide, highlighting the central importance of concurrent substance use (Elbogen and Johnson, 2009, Morgan, 2000). The importance of multiple risk factors is identified in the SMI physical comorbidity literature (e.g. substance use and HIV). Algorithms to predict the broad range of physical comorbidity in this population, including cardiovascular disease, have not been published.

### Risk assessment and intervention

There have been 17 selective and systematic reviews of physical health interventions in SMI (Faulkner et al., 2003, Werneke et al., 2003, Bradshaw et al., 2005, Faulkner and Cohn, 2006, Loh et al., 2006, Faulkner et al., 2007, Ganguli, 2007, Strassnig and Ganguli, 2007, Alvarez-Jimenez et al., 2006, Beebe, 2008, Kemp et al., 2009, Banham and Gilbody, 2010, Maayan et al., 2010, Tsoi et al., 2010, Roberts and Bailey, 2011, Papanastasiou, 2012, Tosh et al., 2014). The most recent included 95 and 7 studies

respectively; no specific trials of risk assessment (e.g. health checks) were reported (Papanastasiou, 2012, Tosh et al., 2014).

There is low uptake of public health screening programs in SMI. A review of 12 studies in the US, Canada, Australia and Europe concluded people with SMI were less likely to access cervical, breast, colorectal or prostate screening than other groups (Howard et al., 2010). A systematic review of HIV testing in SMI reported a very broad range of lifetime testing rates (11-89%, n=13 studies) (Senn and Carey, 2009). Lifetime testing for HCV or HCB was 41% in 200 community SMI patients in the US, with no evidence of increased screening or immunization where high risk sexual or substance use behaviour was documented (Goldberg et al., 2005). Patients with comorbid psychiatric and substance use disorders have been found to have lower rates of immunization, smoking cessation interventions and cancer screening compared to those with a single SMI diagnosis (Druss et al., 2002). A comparison of screening for metabolic risk parameters in patients with SMI compared to patients with diabetes from 8,123 GP practices in England reported significantly lower rates in SMI (74.7%, versus 97.3% p<.001) (Mitchell and Hardy, 2013).

A systematic review of 31 studies concluded people with mental disorder and/or substance use are less likely to receive recommended treatments (including surgery) for comorbid diagnoses than controls (i.e. in general medicine, cardiovascular disease, breast cancer and diabetes) (Mitchell et al., 2009). In the small number of studies that reported bipolar disorder separately, this disparity was not seen (3 studies). The most recent case linkage study of patients with bipolar disorder registered in primary care in Scotland also identified lower than expected rates of treatment (Smith et al., 2013b). Patients with bipolar disorder and CVD and/or hypertension were significantly less likely to be prescribed statins or one or more antihypertensive medicines than controls. These rates do not seem to be associated with problems of access to an appointment and people with SMI are known to make more frequent and longer visits to their GP than general population controls (Daumit et al., 2002).

Disparities in physical health care also exist in hospital and community mental health services. A baseline audit of records on four randomly selected inpatient wards and one CMHT in the largest UK Mental Health NHS Trust identified 100% adult inpatients but only 22% community patients with records of smoking status (Parker et al., 2012). Of the 62 inpatients who said they smoked, only 25% had a record of a conversation about risk and only one had been referred to smoking cessation services. For the five cardio-metabolic risk factors considered most important in SMI (BMI, blood glucose, lipids, blood pressure and smoking status) the rate for a record of assessment of all five was a disappointing 33% (range 1%-77%) in the second National Audit of Schizophrenia [NAS] (Royal College of Psychiatrists, 2014). Wide disparity between NHS Trusts and inadequate rates of

intervention, even where there is a diagnosis of comorbid physical disease remain. Selection of community patients with schizophrenia for the NAS is made by the organisation so may overestimate adherence to the standards as a result of selection bias.

## Chapter Summary

There are multiple risk factors that contribute to early death in SMI. These include those related to psychopathology and illness course, sleep disorders, stress, risk taking, health behaviour, iatrogenic causes and the consequences of stigma and social exclusion. All these risks are potentially modifiable and present targets for intervention. A simple sum of individual risk factors cannot determine the total risk faced by an individual as each risk interacts on a personal and system level to multiply risk. There is as yet no specific algorithm to predict the risk of early mortality in SMI. Despite nearly a decade of practice guidance in the UK highlighting the need for physical health care in SMI, there is very little evidence that physical health risk assessment or intervention is consistently taking place in either primary or secondary care.

# Chapter Five: Identifying the best available evidence on how to educate nurses to undertake a physical health care role in serious mental illness

## Introduction

Researchers are recommended to pay attention to three key phases when developing complex interventions; identifying existing evidence, identifying and developing theory and then modeling processes and outcomes (Medical Research Council, 2008). This chapter examines existing evidence for the education of nurses to support nurse-led interventions in physical wellbeing.

### Background

As discussed earlier, there is as yet no published evidence for the efficacy of screening interventions in SMI although healthcare workers in primary or secondary care are expected to monitor the physical health of all people with SMI at least annually. This role is in step with health policy in England that expects all staff and every healthcare professional working for the NHS to "make every contact count" (Department of Health, 2012, Department of Health, 2014). Staff should "use every contact with an individual to maintain or improve their mental and physical health and wellbeing, whatever their specialty or the purpose of the contact" (Department of Health, 2012 p6).

All nurses in the UK, at the point of registration, are expected to be competent in making a holistic and systematic assessment of physical, emotional, psychological, cultural, spiritual and social needs, including assessing risk and creating a comprehensive plan of care in partnership with the patient and others (Nursing and Midwifery Council, 2010a, Nursing and Midwifery Council, 2010b). The first registrants from nursing courses subject to this new standard graduated in 2014. Therefore the potential impact of curriculum change on the knowledge, attitudes and skills of newly qualified nurses, existing registrants and the physical care of people with SMI is not yet known.

The 2010 standards for nurse education post-date two reviews by the Department of Health that highlighted poor preparation for a physical health care role provided by mental health nurses in secondary care (Department of Health 2006) and for adult nurses to work effectively with patients with SMI in primary care (Department of Health, 2003). The reviews support the UK governments mental health strategy that expects "parity of esteem between services for people with mental and physical health problems" to tackle inequality so that fewer people with mental health problems have physical comorbidity and early

mortality. This strategy has now been enshrined in law (The Health and Social Care Act 2012).

Nurses qualified in the mental health field of practice are recorded under the first level sub part of the UK Nursing and Midwifery Council register. First level nurses are most likely to work directly with patients and their numbers are reported separately from nurse consultants, matrons and managers in NHS workforce statistics. The NHS reported 36,220 first level nurses working in secondary mental health services in England in 2013, with (24%) 14,733 working in community roles (Health and Social Care Information Centre, 2014). Just over 1.5 million people were in contact with secondary mental health services in England between 2011 and 2012. Although the use of the Mental Health Minimum dataset was experimental in this round of data collection and analysis, the largest proportion of patients were reported to be assigned to a 'on-going recurrent psychosis, low symptoms' care cluster (57,706, 13.8% patients) (Health and Social Care Information Centre, 2013). With the majority of clinical contacts reported to take place via Community Mental Health Teams [CMHTs] it is Community Mental Health Nurses [CMHNs] who are the largest number of health care professionals in secondary care in routine clinical contact with SMI patients.

One potential way to achieve a positive impact on the physical health of people with SMI patients is to exploit the opportunity to monitor physical health and offer appropriate intervention through the usual contact and role of mental health nurses [MHNs] (Robson and Gray, 2007, Happell et al., 2011). Surveys indicate that MHNs regard physical health as an important part of their role, but deficits in clinical practice persist hampered by a lack of knowledge, skills and resources and problems facilitating access to care across the primary-secondary care interface (Nash, 2005, Nash, 2010, Howard and Gamble, 2011, Robson and Haddad, 2012). This research largely represents MHNs working in inpatient settings although the largest survey to date (n=585) did not report any significant differences in the 30% of their sample who worked in community teams (Robson and Haddad, 2012).

Although assessment is considered a core feature of mental health nursing practice, reviewers have highlighted a lack of underpinning evidence that is both detrimental to the profession and care of patients (Coombs et al., 2011, Harris and Happell, 1999). Although regulatory agencies define practice standards the structure of a comprehensive mental health nursing assessment and therefore the underpinning knowledge, attitudes and skills required to deliver it has not been standardised. Academics have either focused on one aspect (usually the assessment of risk of suicide or violence) or the philosophy of the approach. MHN assessment has been described as an informal process driven by the need to develop a therapeutic nurse-patient relationship (Muller and Poggenpoel, 1996,

O'Brien, 1999). Research highlights an inconsistent approach to assessment, poor documentation and a lack of focus on physical health care within a whole system approach (Harris and Happell, 1999, Coombs et al., 2011).

I intended to educate mental health nurses to equip them with skills to carry out physical health checks and decide how best to intervene to reduce physical health risk in patients with SMI. I wanted this education to be evidence based so I conducted a systematic review with my fellow student Sheila Hardy (Sheila Hardy was studying for a PhD at the University of East Anglia with a focus on health checks in SMI by health professionals in primary care). The aim of the systematic review was to identify the efficacy of education of qualified healthcare professionals to deliver interventions aimed at improving the physical health of adults with SMI.

**Method**

We undertook a systematic search of the literature in June 2010 using the terms Severe Mental Illness, Physical Health and Education (please see Fig. 5.1 for MEDLINE search terms) utilising the component databases: MEDLINE (Ovid;1950–June 2010; 55 results), CINAHL (EBSCO; 1981–June 2010; 24), AMED (Ovid; 1985–June 2010; 0), Psychinfo (EBSCO; 1806–June 2010; 21), Cochrane (June 2010; 0), WHO (June 2010; 4), OpenSIGLE (June 2010; 216), EMBASE (Ovid; 1980–week 23 2010; 94) and Health Technology Assessments (June 2010; 0). No limitations on year of publication or language were applied and we translated the MEDLINE terms for the other databases. We additionally inspected the references of all identified studies and relevant reviews for other appropriate studies to determine if any material may have been overlooked.

*Inclusion criteria and justification*

- Education to deliver interventions to improve the physical health of people with severe mental illness
- Assessment of the impact of the education package on the healthcare professionals
- Patient specific outcomes

**Figure 5:1 MEDLINE search**

(exp "schizophrenia and disorders with psychotic features"/ OR chronic mental illness.mp. OR chronically mentally ill.mp. OR chronic mentally ill.mp. OR severe mental illness.mp. OR severely mentally ill.mp. OR exp Bipolar Disorder/ OR (bipolar$ adj3 disorder$).ti,ab. OR (bipolar$ adj3 depress$).ti,ab. OR (bipolar$ adj3 illness$).ti,ab. OR (bipolar$ adj3 disease$).ti,ab. OR (bipolar$ adj3 episod$).ti,ab. OR mania.ti,ab. OR manic.ti,ab. OR (hypomanic or hypo-manic or hypomania or hypo-mania).ti,ab. OR cyclothym$.ti,ab. OR (schizophren* or hebephreni* or oligophreni* or psychotic or psychosis).ab,ti.) AND (Health Status/ OR physical health.mp. OR Physical Fitness/ or Health/) AND (exp *education, continuing/ OR (education$ adj2 (program$ or intervention? or meeting? or session? or strateg$ or workshop? or visit?)).tw. OR (behavio?r$ adj2 intervention?).tw. OR (education$ adj1 (method? or material?)).tw. OR ((opinion or education$ or influential) adj1 leader?).tw. OR facilitator?.tw. OR *guideline adherence/ OR (guideline? adj2 (introduc$ or issu$ or impact or effect? or disseminat$ or distribut$)).tw. OR ((effect? or impact or evaluat$ or introduc$ or compar$) adj2 training program$).tw. OR (prompter? or prompting).tw. OR compliance.tw.)

At first, we planned to only include randomised control trials as they are considered to be the highest standard of research evidence to determine the efficacy or effectiveness of a healthcare intervention or service (Health Development Agency, 2009). We searched for RCTs that evaluated the efficacy of the education of qualified health care professionals to deliver interventions aimed at improving the physical health of adults with Serious Mental Illness. As this criteria did not uncover any relevant papers, and the 'most appropriate' (or highest level of) evidence is not necessarily the RCT (Sanson-Fisher et al., 2007), we expanded our criteria to include service evaluations. However, searching for service evaluations did not prove fruitful either, so we removed all study design descriptors from the search criteria while making sure any reported outcomes included some assessment of the impact of the education package on the healthcare professionals as well as patient specific outcomes.

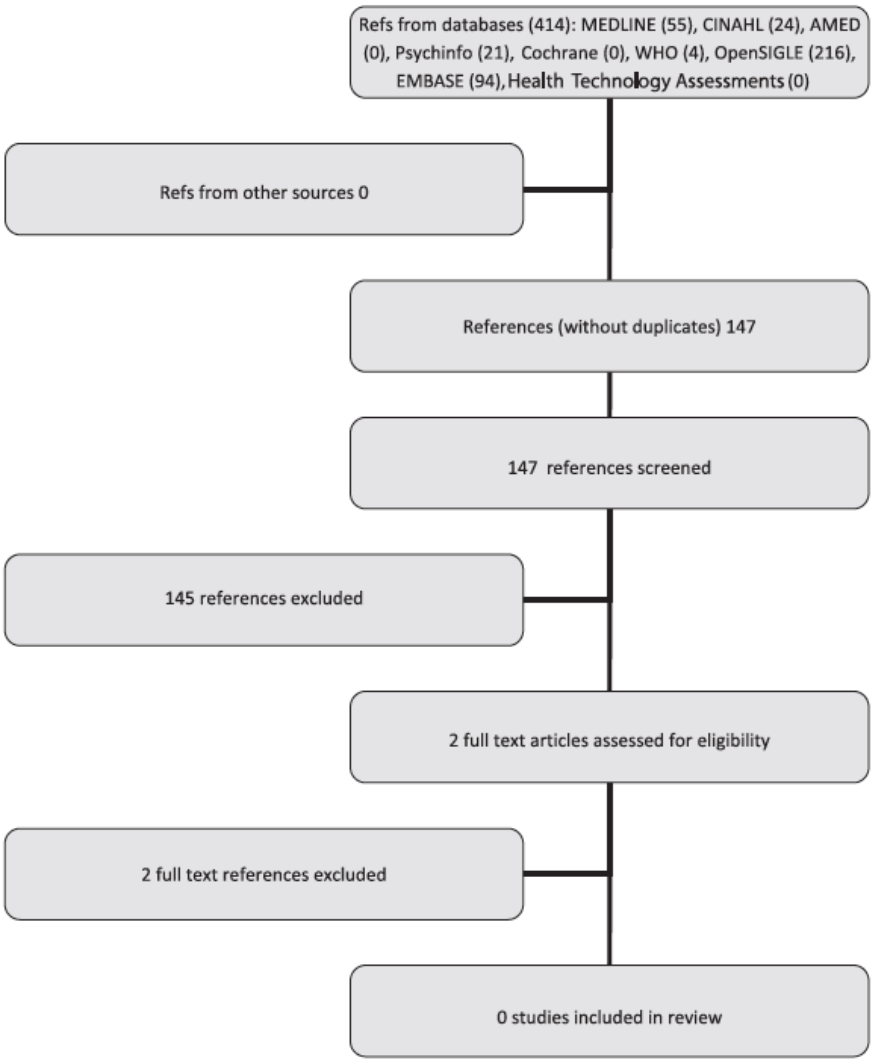
We anticipated that the education packages would involve some face-to-face training (of any duration) backed up by the provision of written materials and potentially prompting processes when the trainees returned to practice. We intended to note the character of training delivery (group, on-to-one, experiential, didactic, duration, location, etc.), the character of the trainer (profession, level of training, etc.), the character of the group (multi or uniprofessional, level of qualifications and area of expertise, etc.) and the provision of support subsequent to the training event (written resources, access to trainers, web groups, etc.).

**Results of systematic search**

We identified 414 publications from the databases: MEDLINE (55), CINHAL (24), AMED (0), Psychinfo (21), Cochrane (0), WHO (4), OpenSIGLE (216), EMBASE (94), HTA (0) and none from other sources. After removing duplicates (267), we independently screened the results and discussed our findings. One hundred and forty-seven papers were excluded because they did not meet our inclusion criteria. There were no difficulties or disputes during this process.

A number of studies were excluded from this review as although there was an implicit education package provided to healthcare professionals, no information was reported on the outcomes of this education with regard to healthcare professionals' knowledge, attitudes and behaviours. The only information that these studies provided was patient-specific outcomes. Therefore no studies were identified as suitable for a systematic review. See flow diagram (Figure 5.2).

**Figure 5:2 Results of systematic review**



### Discussion

It is significant that we were unable to identify any studies. There was an apparent lack of understanding of the importance of disseminating the education component of evidence-based interventions by publication. The impact of any education package aimed at healthcare professionals on their competence (knowledge, attitudes and behaviours) was absent from study reports. Paucity of this information in the public domain may account for the insufficiency of long-term impact for programmes such as the Wellbeing Support Programme [WSP], as the information needed to apply the intervention in practice with fidelity is missing (Smith et al., 2007a, Ohlsen et al., 2005, Smith et al., 2007b).

Providing health checks for people with severe mental illness in the UK has become a requirement of the Quality and Outcomes framework; along with providing health checks for people with other conditions such as diabetes that carry a high risk of developing cardiovascular disease. The difference is however, as well as an abundance of accredited courses available for nurses to monitor people with diabetes, there is an acceptance by nurses that this should be part of their role. The lack of evidence-based training available for qualified nurses to monitor the physical health of people with SMI adds to the view that this is not their responsibility. The lack of evidence to demonstrate that training the nurses will improve patients' health makes advocating any training (should it be available) a difficult task.

Practitioners worry, quite rightly, about patients with SMI committing suicide (Gray et al., 2009). There is an abundance of research regarding interventions to prevent suicide in patients with severe mental illness. A systematic review uncovered no less than 24 studies in this area (Leitner et al., 2008). Given the plethora of papers advocating the importance of monitoring the physical health of people with SMI, we were astonished that both our own attempt and that of Tosh et al. (2010) to evaluate the evidence in this area unearthed no studies. As more patients with SMI die from cardiovascular disease than suicide, it is vital that researchers start to publish details of healthcare professional education in physical health and SMI research.

### Limitations

Our search criteria should have been robust enough to detect relevant studies or service evaluations. It is possible, however, that we have failed to identify small studies and evaluations or studies and evaluations in progress.

## Chapter summary

There is a need not only to develop education for qualified nurses and other relevant healthcare professionals to provide physical health checks and appropriate interventions

for people with SMI, it is also necessary to demonstrate that offering this education will change healthcare professional's behaviour in such a manner that it can be demonstrated to improve patient outcomes.

This study was published as:

Hardy, S. White, J. Deane, K. Gray, R. (2011) Educating healthcare professionals to act on the physical health needs of people with serious mental illness: a systematic search for evidence. *Journal of Psychiatric and Mental Health Nursing.* 18 (8) 721-727.

# Chapter Six: Development of the HIP Programme

## Introduction

An education and clinical decision support intervention was designed to exploit the therapeutic nurse-patient relationship. The aim was to raise the profile of physical health need, support physical health care risk assessment and prompt evidence based intervention *within* existing MHN practice and roles. It was hoped by helping MHNs profile the physical health risks of the SMI patients they work with and directing them towards evidence based interventions to address identified need, an informed physical health conversation could take place to support the patient to choose what to do next. This approach assumes physical health is not being fully attended to and needs to be bought into consciousness to be recognised and acted on. The profile was specifically designed to require minimal education and support and be more sustainable than a program of extensive retraining of the primary care workforce, or the funding of adjunct physical health services across secondary care.

Although pragmatic, this solution was still complex in terms of its development, evaluation and dissemination. It required several interacting components to enable it to target the mental health nurse, the patient and the organisation (e.g. the primary-secondary care interface). It also required a number of behaviours by the nurses tasked with implementing the HIP process and the patients receiving it, including working together and with others to identify appropriate treatment or initiate health behaviour change.

## Development of the HIP and HIP Manual

Building on existing experiential and research knowledge from delivering medication management education and practice change to healthcare professionals over many years, a need to develop a pragmatic intervention to support practice change in physical health in SMI was identified in 2007. A literature review had already been undertaken that highlighted specific areas of comorbidity risk in SMI and the potential of the MHN workforce to address these (Robson and Gray, 2007). From this paper and discussion between Professor Richard Gray, Dr Martin Jones and myself, 28 risk parameters were identified as a priority for assessment in SMI (Figure 6.1). A series of literature searches then established the normal and abnormal ranges for each of these parameters, and the recommended action/guidance for parameters found to be abnormal. A 27-item gender specific profiling tool was designed that would enable mental health nurses to use ‘red flag’ aspects of physical health when undertaking a physical health risk assessment with SMI patients. We believed it was important that the HIP was not just a checklist for assessment but prompted evidence based action for abnormal findings. The HIP was therefore designed to direct the nurse and patient to select the action or actions to take

next that best suited the individual by providing a menu of possible interventions to select from. Citations were provided for all parameter ranges and recommended actions and where there was the potential of different tests being used in practice (e.g. for blood glucose) a range of alternatives were provided (Please see Appendices 1 and 2 for a copy of the HIP and the HIP Manual).

**Figure 6:1 Physical health risk parameters included in the HIP**

1. Body Mass Index
2. Waist Circumference
3. Pulse
4. Blood Pressure
5. Temperature
6. Liver Function Tests
7. Lipid levels
8. Glucose
9. Cervical smear (female)
10. Prostate and testicles check (male)
11. Sleep
12. Teeth
13. Eyes
14. Feet
15. Breast check (female and male)
16. Menstrual cycle (female)
17. Smoking status
18. Exercise
19. Alcohol intake
20. Diet: 5-a-day
21. Diet: fat intake
22. Fluid intake
23. Caffeine intake
24. Cannabis use
25. Safe sex
26. Urine
27. Bowels
28. Sexual satisfaction

The considerable practice and education experience of all three authors was used when determining how to present the HIP to mental health nurses. The only other physical health tool available, known as the Rethink tool (Phelan et al., 2004), extends over 9 pages and its size had been reported to us as a barrier to its use from those we knew who had tried to implement it. Practitioners regularly complain about the amount of administrative paperwork they are required to complete in their role. I had witnessed the benefits of presenting assessment information in a systematic format from my experience of the use of side-effect scales in nurse-led SMI medication management clinics. This approach had been welcomed as a way to improve interface communication by both psychiatrists and GPs. We wanted the HIP to be used as a support to practice and not seen as yet another administrative task or form to fill in. We therefore decided to keep the HIP to one side of a sheet of paper. We also decided to produce the HIP as a paper version, rather than a software or online version. This was to avoid problems in dissemination and use due to NHS governance and the low levels of use of information technology in clinical MHN practice. Use of electronic record systems was at a very early stage in secondary mental health services in 2007. A variety of different software was in use with its purpose largely to collect data for quality assurance purposes, rather than to

support clinical decision-making. This is very much in contrast to primary care where it would have been impossible to introduce a paper-based tool. It was believed that a paper-based tool, completed on one side of A4 paper could easily be photocopied and sent to the patient's GP or other agency with a cover letter to provide supporting evidence for any recommended referral.

The HIP has columns indicating the variable at risk for assessment (e.g. smoking status), level (result), Green (e.g. 'non smoker'), Red (e.g. 'passive smoker/smoker') and the recommended action for red group (e.g. advice that all smoking is associated with health risks, refer to NHS smoking cessation service). The HIP is intended to be completed at least annually, the recommended frequency of screening for patients with SMI in England. There was a need to consider issues of intellectual property against motivation to disseminate the HIP as widely as possible and encourage healthcare professionals to use it. The *Journal of Psychiatric and Mental Health Nursing* is the leading journal for mental health nurses in the UK. A paper describing the development of the HIP and its initial dissemination was published (White et al., 2009). A copy of the HIP was not included in the publication but released to anyone in contact with me and agreed to provide feedback in future via email. This continues today and the on-going dialogue with the large network of users is helpful in regularly updating the HIP. For example in 2012 changes were made to the blood pressure parameter and in 2014 to the diet parameters, due to new published guidance and feedback from users.

A comprehensive HIP Manual was written expanding in detail the evidence for each of the HIP Parameters and the recommended action (Appendix 2). Specific information about how to complete and use the HIP in practice is included. The manual has been adapted for different purposes, for example there is a version for primary care (to support the HIP-PC) and versions to support the Commissioning for Quality and Innovation [CQUIN] payment targets in specific NHS Trusts where the HIP is now implemented.

## Development of the education part of the HIP Programme

The aim was to develop an education package for mental health nurses caring for people with SMI to enable them to offer better physical care through use of the HIP in their practice. As discussed earlier there was no published evidence to draw on to inform this process. In a systematic review of the outcomes of educational meetings, the use of mixed didactic and interactive methods was found to be more effective in changing professional behavior than didactic methods alone (Forsetlund et al., 2009). Harnessing the motivation and enthusiasm of participants for a topic through discussion has been

identified as important in supporting implementation of learning into practice after continuing professional development (Lee, 2011).

Educational materials were designed (together with Professor Richard Gray and Dr Martin Jones) that integrated didactic teaching with experiential activities and discussion. These materials were initially used in a series of two national 'train the trainer' events in October 2007 and February 2008 at the University of Aston Business School, Birmingham. Training in presentation skills was included and the workshops were funded by Bristol Myers Squib and Otzuka Pharmaceuticals UK. The learning activities were delivered by all three of us was attended by 24-experienced MHN from different mental health provider organisations around the UK (59% from community teams). The aim was to enable delegates to deliver at least three workshops for MHNs on return to their organisations. In 2009 Bristol Myers Squib disbanded its nurse education department following a Europe wide marketing strategy review and ceased their support of dissemination of the programme.

Building on previous extensive education experience and experience from the 'train the trainer' stage, the final HIP Programme training package was re-written by me as a series of four PowerPoint presentations with a view to flexible delivery i.e. selecting from the slides to meet the needs of mental health nurses and the time available to teach them (i.e. a 1-4 hour workshop).

The intended learning outcomes were:

At the completion of the training workshop participants will be able to:

1. Explain why physical health is important in serious mental illness and nurses need to act.
2. Use the HIP and HIP Manual to systematically examine the physical health of individual patients and identify the best next steps to take for items that flag red.
3. Describe how to engage patients in health behaviour change and work with them to develop a patient specific health action plan
4. Construct at least three action points to support the implementation of the HIP into their practice.
5. Know what to do every time a HIP is completed with a patient
6. Know how to access further information and resources to support their physical health care practice.

The following four presentations were created and adapted by me from the materials used in the initial "train the trainers" dissemination of the HIP:

1. Background: Physical health is important in serious mental illness and nurses need to act.
2. Review of the Physical Health Improvement Profile (HIP) Parameters
3. Using the HIP to engage patients with serious mental illness in health behaviour change.
4. Developing an action plan to take away.

The first presentation supports a didactic presentation of the evidence relating to physical comorbidity, mortality and risk in SMI (although discussion of practice experience and views of participants is actively facilitated). The final few slides in this first slide set were developed in cooperation with Dr Sheila Hardy (who adapted the HIP for primary care) and include a brief overview of type II diabetes, heart disease, stroke and chronic obstructive pulmonary disease. The other three presentations support experiential learning through use of the HIP and HIP Manual to investigate how to manage a variety of practice scenarios related to “flagged red” items on the HIP (2), how to introduce the HIP and how to use the results to agree an individual health action plan (3) and support to identify and share potential ways to reduce anticipated barriers and increase levers to implementation (4).

## Evaluation of the HIP education package

I initially piloted and refined the HIP Programme presentations in sessions in the undergraduate post and pre-registration modules that I deliver at the University of Hull. These materials have now been used for a variety of MHN audiences locally, regionally, nationally and (translated versions) internationally. In 2012, I delivered the HIP in a regional masterclass as part of a series of workshops that aimed to provide knowledge and skills matched to the NMC essential skills cluster competencies to mental health nurses from the Yorkshire and Humber NHS region.

### Method

A pre- and post-test design was used. All 53 nurses who attended were asked to complete a questionnaire regarding their current knowledge of physical health in SMI just before the workshop started. This was repeated on immediate completion of the workshop, together with a post-evaluation of the workshop content, materials, and delivery. A multiple-choice format was used for knowledge questions and a Likert scale for the attitudinal items with spaces for answers to open-ended questions. Paired questionnaires (from the same participant) were identified using numbered forms. No personal data was

collected although some brief details of the participants gender, age, length of MHN experience and service context were requested

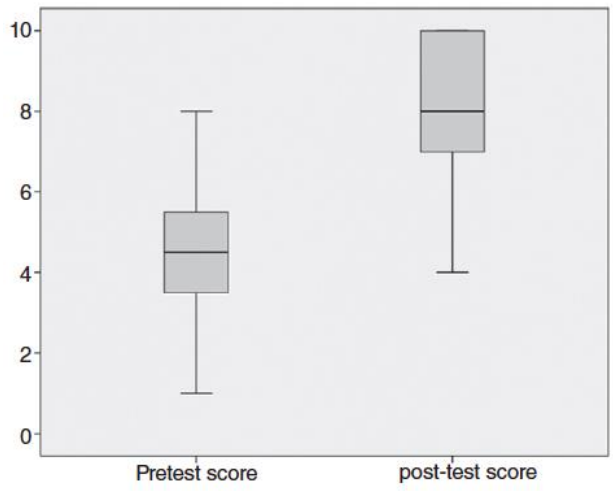
Permission to undertake the study was granted by the School of Health and Human Sciences Research Ethics Panel at the University of Huddersfield. Information about the study was verbally exchanged with the participants at the beginning of the workshop, with consent presumed if questionnaires were completed and returned.

Each participant was assessed on their response to 10 equally weighted multiple-choice questions relating to physical health assessment in SMI and the recommended action to take if a physical health parameter was at risk (Knowledge MCQ). A maximum of 10 marks could be obtained from the summation of answer scores.

**Results**

The questionnaires were subject to statistical analysis using SPSS (version 18.0). Thirty-nine questionnaires were submitted at the beginning of the workshop (74%), and 44 at the end (83%), the higher number reflects participants who arrived late. Responses submitted before and after the intervention were paired and 38 (72%) participants were included in the analysis as they provided valid responses. Thirty-six participants were female (78.3%) and 10 participants (21.7%) male. The majority of participants (23; 47.9%) had been working in health care for less than 5 years. Service contexts were approximately equally represented, with 18 inpatient nurses (38.3%), 14 community nurses (29.8%), and 15 (31.9%) who recorded their context as “Other.”

**Figure 6:2 Pre and post test scores of knowledge MCQs**




The mean score recorded pretest was 4.47(SD 1.59) and post-test was 8.11(SD 1.67) .The spread of pre- and post-scores is shown in Figure 6.2. A paired samples t test

found a statistically significant difference between pre- and post-scores ($p < .001$, 95% confidence interval 3.00, 4.58). Although all groups of participants recorded higher post-test scores indicating knowledge transfer participants indicating they were from the inpatient context demonstrated less improvement (2.84 points: SD 2.31) than those from the community (4.27 points :SD 1.19) and who had indicated “other” (4.36 points :SD 3.04).

All participants except one reported themselves to be either “satisfied” or “very satisfied” with both the topic delivery and with the content of the workshop and its relevance to practice, with 38 respondents (77.6%) reporting themselves to be “very satisfied”.

### Discussion

This small study demonstrated knowledge gain post workshop and also provided useful evidence of the range of scores for the knowledge MCQs that could potentially aid the analysis of knowledge gain in future. It is interesting that inpatient MHNs had less knowledge to gain, but maybe not surprising as inpatient MHNs tend to be more recently qualified and more likely to have up to date clinical physical health assessment skills (e.g. due to regular monitoring of vital signs in their practice). It is not clear why some workshop attendees indicated their work context as ‘other’, this could potentially be tertiary (e,g. forensic) services. There were limitations regarding the MCQ that was not psychometrically developed. Post session learning has a recency effect (Deese and Kaufman, 1957). The findings are encouraging but do not indicate if knowledge gained was retained or had any impact on future practice.

## First pilot of the HIP in a nurse-led clinic in secondary care

A senior mental health nurse trained in the first “train the trainer” event in 2007 piloted the HIP in a nurse-led ‘medication management’ clinic for community patients with SMI in Scotland, alongside one other mental health nurse she had trained.

### Method

Frances Shuel [FS], and I obtained governance approval for a service evaluation that included a retrospective documentation audit of case notes for all patients where the HIP had been implemented in the clinic, semi-structured interviews with these patients and their secondary care clinicians and a postal survey of their GPs. Patients were assessed between 13/11/2007 and 17/09/2008 and consented to their anonymous data being used following information exchange from FS.

Patients who had used the HIP, their psychiatrists and MHNs who worked in the clinic and/or two acute inpatient wards at the hospital were invited to participate in short semi-structured interviews. GPs were invited to complete a short postal questionnaire. After being reminded that anonymous data was being collected and asked to consent separately to this part of the study, participants were asked for feedback about their experience of the HIP. Open-ended questions included what they thought about the tool, what happened next, if they thought it had had any effect on communication with others and if they thought the tool could be improved.

Each interview was conducted by FS on a one-to-one basis in a private room over approximately 10-20 minutes. Answers were recorded verbatim on to an anonymous data collection form for later collation and analysis. Analysis was undertaken of anonymised data using SPSS v15 and content analysis of the interview records by all three authors of the HIP. Where a patient identified that action had been taken about an out of range parameter following use of the HIP, FS was asked to provide further information from the case notes if available.

The study did not meet the criteria of a research study as defined by the National Patient Safety Agency [NPSA] National Research Ethics Service (NPSA, 2008) and was, therefore, approved as a clinical audit and service evaluation by the Hospital's Medical Director, including permission to publish data and results.

**Results**

All 31 patients agreed to participate in the semi-structured interviews that took place with FS at their next visit to the clinic. All MHNs (with the exception of FS who conducted the interviews) and psychiatrists working in the clinic and/or wards at the hospital agreed to take part in the interviews (n=8; n=4). 57% GPs returned the short postal questionnaires (n = 12).

One hundred and eighty nine physical health issues were identified in this first case series (mean 6.1 per patient). Please see Table 6.1 for details of the frequency of issues reported. The items most frequently flagged 'red' on the HIP, suggesting that intervention was required, were body mass index [BMI] (n = 24), breast self-examination (n = 23), waist circumference (n = 21), pulse (n = 14) and diet (n = 13). At least one physical health issue was identified in every patient. There was a high prevalence of obesity, poor diet (particularly eating five portions of fresh fruit and vegetables a day) and lack of exercise. Breast self-monitoring was inadequate and cardiac problems (tachycardia) were common.

**Table 6:1 Frequency of HIP parameters (N=31)**

| Rank | Parameter | Red % (*n*) | Green % (*n*) | Not assessed or applicable, % (*n*) |
|---|---|---|---|---|
| 1 | Body mass index | 77.4 (24) | 22.6 (7) | 0 (0) |
| 2 | Breast check (female and male) | 74.2 (23) | 22.6 (7) | 0 (0) |
| 3 | Waist circumference | 70.0 (21) | 30.0 (9) | 3.2 (1) |
| 4 | Pulse | 45.2 (14) | 54.8 (17) | 0 (0) |
| 5 | Diet: 5-a-day | 41.9 (13) | 58.1 (18) | 0 (0) |
| 6 | Exercise | 29 (9) | 67.6 (21) | 3.2 (1) |
| 7 | Lipid levels | 25.8 (8) | 73.3 (22) | 3.2 (1) |
| 7 | Sleep | 25.8 (8) | 74.2 (23) | 0 (0) |
| 7 | Smoking status | 25.8 (8) | 64.5 (20) | 9.7 (3) |
| 10 | Alcohol intake | 19.4 (6) | 71 (22) | 9.7 (3) |
| 10= | Prostate and testicles check (men only) | 19.4 (6) | 51.6 (16) | 29.1 (9) |
| 12 | Feet | 16.1 (5) | 83.9 (26) | 0 (0) |
| 12= | Diet: fat intake | 16.1 (5) | 83.9 (26) | 0 (0) |
| 12= | Sex satisfaction | 16.1 (5) | 29.0 (9) | 54.8 (17) |
| 15 | Blood pressure | 12.9 (4) | 87.1 (27) | 0 (0) |
| 15= | Teeth | 12.9 (4) | 87.1 (27) | 0 (0) |
| 15= | Eyes | 12.9 (4) | 87.1 (27) | 0 (0) |
| 15= | Bowels | 12.9 (4) | 87.1 (27) | 0 (0) |
| 19 | Liver function tests | 9.7 (3) | 83.9 (26) | 6.4 (2) |
| 19= | Glucose | 9.7 (3) | 87.1 (27) | 3.2 (1) |
| 19= | Menstrual cycle (female) | 9.7 (3) | 19.4 (6) | 70.9 (22) |
| 22 | Caffeine intake | 6.5 (2) | 90.3 (28) | 3.2 (1) |
| 22= | Cannabis use | 6.5 (2) | 90.3 (28) | 3.2 (1) |
| 24 | Safe sex | 6.5 (2) | 41.9 (13) | 51.6 (16) |
| 25 | Cervical smear | 3.2 (1) | 25.8 (8) | 70.9 (22) |
| 26 | Urine | 3.2 (1) | 96.8 (30) | 0 (0) |
| 27 | Fluid intake | 3.2 (1) | 96.8 (30) | 0 (0) |
| 28 | Temperature | 0 (0) | 100 (31) | 0 (0) |

Mean BMI and waist circumference were indicative of obesity, although average lipid and glucose levels were normal (Figure 6.3). Smoking, alcohol and cannabis use were recorded in a smaller number of patients than might be expected. The two items most often omitted from completion by the HIP by the nurse were safe sex and sexual satisfaction. These were not determined in at least half of all patients but where satisfaction was assessed, over a third reported experiencing problems.

**Figure 6:3 Mean scores for HIP parameters (N=31)**

| Parameter | Mean (SD) |
|---|---|
| Body mass index | 30.53 (5.14) |
| Waist circumference | |
| Group | 98.10 (15.97) |
| Male | 99.07 (13.42) |
| Female | 95.96 (21.61) |
| Pulse | 101.83 (13.54) |
| Systolic BP | 120.26 (13.30) |
| Diastolic BP | 70.80 (9.60) |
| Glucose | 5.56 (0.81) |
| Lipids | |
| TC | 4.97 (1.44) |
| LDL-C | 2.86 (1.00) |
| HDL-C | 1.93 (1.72) |
| TG | 1.35 (.55) |

There were 14 referrals for potentially serious conditions including raised glucose and lipids, hypertension and cardiac problems. Individualised care was planned and delivered with each patient based on the profile. Twenty-eight discreet interventions were used that included providing advice, promoting health behavioural change, performing an electrocardiogram and making a referral to professional colleagues. The range and frequency with which each intervention was used is shown in Table 6.2.

Participants in the semi-structured interviews and GP survey were largely positive about the HIP process. Patients expressed surprise that the MHN was paying attention to their physical health but liked the opportunity to have a physical health conversation. There was evidence from the patient responses and the case notes that the nurse went on to plan care to address physical health need. Several patients reported positive outcomes as result of changes to their health behaviour or medication following use of the HIP (e.g. weight loss, lower blood pressure). Negative comments included one from a patient about the (financial) cost of having to buy new clothes after losing weight and four (50%) mental health nurses who were concerned about the potential additional workload of implementation. All four psychiatrists commented positively about the HIPs comprehensiveness and evidence base. The GPs also liked the comprehensiveness and welcomed the HIP as a way of sharing of data to benefit them. Two GP's thought the amount of information on the form meant they could miss red-flagged parameters and one suggested the HIP or accompanying letter should highlight which interventions they were required to do.

**Table 6:2 Interventions delivered to patients following the HIP**

| Rank | Interventions delivered (item 'red' flagged) | Number of patients, % (*n*) |
|---|---|---|
| 1 | Advice on self-examination/check risk factors for breast cancer (breasts) | 68 (21) |
| 2 | Advice and support on diet and exercise, referral to local weight/exercise management programme, consider medication review (obesity) | 61 (19) |
| 3 | Electrocardiogram [ECG] performed (tachycardia) | 42 (13) |
| 4 | Offer recommendations on the reduction of health risks with 5-a-day (diet 5-a-day) | 39 (12) |
| 5 | Advice that smoking is associated with significant health risks (smoking) | 26 (8) |
| 6 | Refer to GP for appropriate treatment (lipid levels) | 23 (7) |
| 6= | Offer recommendations on sensible daily alcohol intake (alcohol) | 23(7) |
| 8 | Address potential barriers to accessing and eating fruit/vegetables (diet 5-a-day) | 19 (6) |
| 9 | Confirm prostate screen at fixed intervals for patients over 50 years of age | 16 (5) |
| 9= | Refer to NHS stop smoking services | 16 (5) |
| 9= | Recommend 30 min activity 5 days a week (exercise) | 16 (5) |
| 12 | Encourage regular visits to the dentist (teeth) | 13 (4) |
| 12= | Encourage visits to optician (eyes) | 13 (4) |
| 12= | Determine patient's level of sexual activity (sexual satisfaction) | 13 (4) |
| 15 | Clarify sleep problems and provide education of good sleep hygiene and benefits of sleep diary (sedation) | 6 (2) |
| 15= | Check for symptoms of diabetes and test for ketones if symptoms are present (glucose) | 6 (2) |
| 15= | Check for symptoms of caffeinism or caffeine toxicity (caffeine) | 6 (2) |
| 15= | Offer advice to gradually reduce caffeine intake and limit withdrawal effects (caffeine) | 6 (2) |
| 15= | Check of gastrointestinal symptoms (bowels) | 6 (2) |
| 20 | Agree and implement plan with the patient/carer (diet 5-a-day) | 3 (1) |
| 20= | Advice on reducing fat intake and achieving a well balanced diet (diet fat intake) | 3 (1) |
| 20= | Agree and implement plan with patient/carer (diet fat intake) | 3 (1) |
| 20= | Include other members of the multi-disciplinary team, e.g. occupational therapists (diet fat intake) | 3 (1) |
| 20= | Refer to GP for further investigations (blood pressure) | 3 (1) |
| 20= | Identify if patient is in high risk group for sexually transmitted diseases [STIs] (safe sex) | 3 (1) |
| 20= | Identify in patient is engaging in behaviours that increase risk of STIs (safe sex) | 3 (1) |
| 20= | Provide sexual health advice (safe sex) | 3 (1) |
| 20= | Encourage fluids (bowels) | 3 (1) |
| 20= | Perform systematic assessment (sexual satisfaction) | 3 (1) |

## Discussion

This pragmatic service evaluation provided evidence that the HIP is a useful clinical tool that enables MHNs to profile and plan physical health care and treatment for patients with SMI.

Patients welcomed and actively participated in the process. Rates of physical health problems observed using the HIP were broadly similar to a study of patients in the North East of England receiving antipsychotics in primary care (Macklin et al, 2007). Some of the findings concerning lower than expected rates of smoking and high levels of tachycardia may be related to the sample, who were all drawn from those attended an outpatient clinic for medicines management (i.e. that they had already been engaged in smoking cessation interventions and that they were likely to be prescribed an anticholinergic antipsychotic (e.g. clozapine). The comments from the patients and secondary care record evidence suggested that many of the problems identified in the HIP process was new information to the patient and secondary care team and (possibly) primary care, e.g. where a decision was taken to initiate statins. We received very positive qualitative feedback from patients, mental health nurses, psychiatrists and GPs about the utility of the tool.

Limitations included possible bias in the data collection method. All data was collected by FS who was very supportive of the HIP Programme and had introduced the HIP to her own her own and others' practice. Patient participants may have been keen to provide positive comments about their care to the person who was providing it. Clinicians interviewed were those who had an existing professional relationship with FS, in some cases she was their line manager. It was not possible to compare identified physical problems with previously diagnosed comorbidities as access to all records was not possible within the confines of the permission granted for the audit (i.e. both primary and secondary care). Nevertheless this study provided enough evidence of acceptability and utility for a clinical trial of the HIP Programme. It also suggested the need for a greater focus on having conversations about sex and the need to make sure barriers to implementation are afforded enough time for discussion and problem solving in the HIP workshops (highlighting how to communicate with GPs and MHN workload issues) if this is not raised by participants. At an organisational level shared care pathways between primary and secondary care that clearly identify roles and responsibilities for physical health care in SMI may help to address some of the role confusion that was highlighted by a few of the GPs.

## Chapter summary

This chapter has described the development of the HIP Programme intervention designed to target physical wellbeing in SMI through the existing role of the mental health nurse from the initial idea in 2007. Pragmatic evaluations of the impact of the 'train the trainer' method and evaluation of implementation of the HIP with 31 patients in one secondary care nurse-led community clinic provided evidence of acceptability and utility. Since this PhD study commenced in early 2009, the data from the service evaluation has been analysed and published in a peer-reviewed journal and used to inform a grant application to the National Institute for Health Research [NIHR] for a clinical trial. A small opportunistic study demonstrated that the final education package significantly improved MHNs physical health knowledge at the end of a 3-hour version of the HIP workshop.

The development and piloting work described in this chapter was published as:

White, J., Gray, R. & Jones, M. 2009. The development of the serious mental illness physical Health Improvement Profile [HIP]. *Journal of Psychiatric and Mental Health Nursing,* 16**,** 493-498.

Shuel, F., White, J., Jones, M. & Gray, R. 2010. Using the serious mental illness health improvement profile [HIP] to identify physical problems in a cohort of community patients: A pragmatic case series evaluation. *International Journal of Nursing Studies,* 47**,** 136-145.

White, J., Hemingway, S. & Stephenson, J. 2013. Training Mental Health Nurses to Assess the Physical Health Needs of Mental Health Service Users: A Pre- and Post test Analysis. *Perspectives in Psychiatric Care*, Early View 25 NOV 2013 DOI: 10.1111/ppc.12048, E1-8.

# Chapter Seven: Further evaluations of the HIP in practice

## Introduction

Frances Shuel [FS] delivered HIP training to all eight mental health nurses working across the two acute inpatient wards of the hospital in Scotland that she managed within her role. With the agreement of the multidisciplinary teams and under her direction, a practice standard was agreed to complete a HIP for every patient on admission to either ward, or as soon afterwards as was practically possible. As with the nurse-led (community) clinic data described in the previous chapter, FS transcribed data from each completed paper HIP into an excel database with a view to future evaluation. Patients were assigned a unique number in the database that could be linked to their case records by FS if required. Details of the patient's gender, date of birth, diagnosis, medication and date of completion of the HIP were included, alongside the results of each parameter assessed using the HIP. A free text "comments" field was used to record information about interventions.

### Method

FS obtained governance permission for a retrospective clinical audit of the HIP inpatient database in July 2010. I analysed the (anonymised) data after cleaning it and then importing it to SPSS 17 from Excel. Duplicates were removed (if there had been more than one HIP completed for the same patient). Several data entry errors were observed at this stage and resolved by communicating with FS (e.g. measurement queries, missing data). Unfortunately, it was not possible to revisit all the original forms to check and/or repeat the original data entry so interventions were only captured if FS had considered them important.

### Results

108 'first contact' HIPs were completed between November 2007 and June 2010 for patients admitted to the two inpatient wards. Characteristics of the sample are summarised in Table 7.1.

**Table 7:1 Characteristics of the acute inpatient sample who received a HIP (N=108).**

| | N (%) |
|---|---|
| Age (mean, SD) | 43 (11) |
| Male gender | 71 (66) |
| Ethnicity (white) | 106 (98) |
| Diagnosis<br>Schizophrenia (or schizoaffective disorder)<br>Bipolar disorder<br>Other (e.g. borderline personality disorder,<br>substance and/or alcohol use disorder, depression) | 72 (67)<br>14 (13%)<br>22 (20%) |
| Psychiatric Medication<br>Prescribed medication<br>Prescribed antipsychotic medication<br>Prescribed no medication | <br>98 (96)<br>91 (84)<br>4 (3.7) |

Please see Table 7.2 for a summary of the HIP parameters that flagged red in this cohort. 934 physical health issues were identified per patient (mean 11.43 sd = 5.08, 95% confidence interval ±0.76).

Every patient had at least 2 parameters that flagged red, indicating the need for intervention. Although there was a slightly different distribution of parameters compared to the HIP, 31 CVD risk parameters continued to predominate. Four of these (BMI, lipids, waist circumference, smoking) flagged red in over half of the sample, along with the diet and self-examination parameters. However, in common with the community (HIP 31) sample, mean blood pressure, glucose and cholesterol values were within their normal range (Table 7.3).

There was evidence of intervention to improve health status from information entered in the comment fields. For example, of 41 patients with an abnormal pulse, 29% (12) had a comment to indicate they were then found to have an abnormal electrocardiogram [ECG] that led to a change in medication. Of 21 patients who reported sexual dissatisfaction through use of the HIP, 71% (15) had raised prolactin and 6 went on to try a change of antipsychotic. Of patients who were asked, 20% (17) reported not practicing safe sex so the opportunity to have a conversation with them about this and exchange information was exploited.

**Table:7:2 HIP parameters that flagged red in the inpatient HIP cohort (n=108)**

| *Rank* | *Item* | *Not assessed* | *Men (%) n=71* | *Women (%) n=37* | *Total (%) n=108* |
|---|---|---|---|---|---|
| =1 | Diet (fat intake) | - | 68 (96%) | 29 (78%) | 97 (90%) |
| =1 | Breast check | - | 69 (97%) | 20 (54%) | 89 (82%) |
| =3 | Body Mass Index | - | 53 (75%) | 23 (62%) | 76 (70%) |
| =3 | Prostate/testicles check[a] | - | 50 (70%) | - | - |
| 4 | Diet (5 a day) | - | 47 (66%) | 24 (65%) | 71 (66%) |
| =5 | Lipids | 13 (12%) | 43 (66%) | 19 (63%) | 62 (57%) |
| =5 | Waist circumference | - | 41 (58%) | 21 (58%) | 62 (57%) |
| =6 | Smoking status | - | 39 (55%) | 19 (52%) | 58 (54%) |
| =7 | Alcohol | - | 41 (58%) | 8 (22%) | 49 (45%) |
| =8 | Feet | - | 35 (49%) | 13 (35%) | 48 (44%) |
| =9 | Teeth | - | 33 (46%) | 11 (30%) | 44 (41%) |
| 10 | Urine | 1 (1%) | 33 (46%) | 10 (28%) | 43 (40%) |
| 11= | Exercise | - | 26 (37%) | 15 (41%) | 41 (38%) |
| 11= | Pulse | - | 31 (44%) | 10 (27%) | 41 (38%) |
| 12 | Caffeine intake | - | 23 (32%) | 13 (35%) | 36 (33%) |
| 13 | Eyes | - | 24 (34%) | 8 (22%) | 32 (30%) |
| 14 | Menstrual Cycle | 1 (1%) | - | 10 (28%) | - |
| 15 | Bowels | - | 19 (27%) | 9 (24%) | 28 (26%) |
| 15= | Safe sex | 22 (20%) | 11 (20%) | 6 (19%) | 17 (25%) |
| 16= | Cannabis use | - | 20 (28%) | 7 (19%) | 27 (25%) |
| 16= | Cervical smear[b] | 1 (1%) | - | 9 (25%) | - |
| 17 | Fluid intake | - | 19 (27%) | 6 (16%) | 25 (23%) |
| 18 | Glucose | 5 (5%) | 14 (61%) | 9 (39%) | 23 (21%) |
| 19= | Sex satisfaction | 30 (28%) | 14 (20%) | 7 (24%) | 21 (19%) |
| 19= | Sleep | 6 (6%) | 8 (12%) | 8 (23%) | 16 (19%) |
| 20 | Blood pressure | - | 13 (18%) | 6 (16%) | 19 (18%) |
| 21 | Temperature | - | 5 (7%) | 5 (13%) | 10 (9%) |
| 22 | Liver Function[c] | | | | 0 (0%) |

a = men only, b = women only , c = All patients have liver function tests on admission as standard.

**Table 7:3 Cardiovascular risk in the inpatient HIP cohort (N=108)**

| | N | Minimum | Maximum | Mean (SD) |
|---|---|---|---|---|
| **Body Mass Index** | **108** | **18.0** | **48.5** | **29.7 (6.6)** |
| **Waist circumference (cm)** | **108** | **70.0** | **155.0** | **98.5 (16.3)** |
| **Pulse** | **108** | **66** | **151** | **100.5 (14.9)** |
| Systolic Blood Pressure | 108 | 85 | 174 | 124.1 (15.4) |
| Diastolic Blood Pressure | 108 | 50 | 99 | 75.8 (9.9) |
| Random Plasma Glucose | 103 | 3.0 | 12.5 | 5.9 (1.4) |
| HBA1C | 75 | 3.9 | 6.8 | 5.2 (0.5) |
| Total cholesterol | 97 | 2.3 | 8.9 | 4.9 (1.3) |
| HDL cholesterol | 96 | 0.6 | 7.8 | 1.6 (1.1) |
| **LDL cholesterol** | **96** | **0.9** | **5.6** | **2.9 (1.0)** |
| **Triglycerides** | **97** | **0.5** | **10.4** | **2.2 (1.5)** |
| **Smoking** | **108** | | **58 (54%) smokers** | |

## Discussion

Compared to the 16,240 patients admitted to 136 acute wards across England reported in the City 128 'Safewards' Cohort (Bowers et al., 2006), our sample had a higher proportion of males (0.66 versus 0.49), patients with a diagnosis of schizophrenia (0.67 versus 0.32) and white ethnicity (0.98 versus 0.67). Duration of illness was not reported in the City 128 study but in 73% of our sample it was more than 10 years. This may explain the relatively older age of our sample and high number of comorbidities detected.

Mean body mass index, waist circumference, pulse and raised triglycerides were similar to that seen in the (community) HIP 31 sample, as were smoking rates. Smoking at 55% was comparable to that reported in the sample recruited from primary care SMI registers from eight sites across England and Wales for the Wellbeing Support Programme (51%, n = 479) (Smith et al., 2007a).

Reported levels of alcohol use indicating a need for intervention occurred in just under half this acute inpatient sample (45%). This may have reflected acuity and drinking as a

coping strategy just prior to admission or been skewed as a result of those admitted for detoxification. It is also possible that the number of alcohol units were inaccurately recorded on the HIP form by the nurse (units per day are required, not per week requiring an estimation based on information disclosed). Similar to the results of the HIP 31 study, the parameters that were most often omitted were those related to safe sex and sexual satisfaction. This adds weight to the earlier observation that there are barriers to nurses and patients having conversations about sex.

Limitations are similar to those described for the HIP 31 cohort and included possible bias in the data collection and recording methods. FS is an advocate of the HIP Programme and had introduced it and decided what data to collect for evaluation purposes at the hospital. Data was not available on patients' previous comorbid physical diagnoses, the outcome of interventions or about patients where a HIP had not been completed (presumably some patients had refused or nurses were unable to engage some in the whole process). The sample was not restricted to patients with SMI because it was a 'real practice' cohort of those admitted for acute inpatient care. Although there were some repeat HIP records in the database, numbers of these were far too small to enable any meaningful comparison so the evaluation was restricted to 'first contact' HIPs.

This further opportunistic evaluation of a convenience sample added to the evidence of utility and acceptability of the HIP, supporting its ongoing use in clinical settings. Community patients already engaged in attending a medication management clinic in secondary care had similar comorbidity incidence to previous evaluations of primary care cohorts receiving antipsychotic medication, but less than that reported in epidemiological studies. Patients in acute inpatient settings with a broader range of diagnoses than SMI alone had a worse physical health profile than community patients but were still willing to engage in the HIP process. For some patients intervention following implementation of the HIP for potentially serious problems may have prevented premature mortality. It appeared that the HIP could be successfully implemented through a brief cascade of training without reconfiguring services and roles. However, this work indicated that the HIP Programme training would benefit from more of a focus on the importance of initiating conversations with patients about their sexual health (with discussion of potential barriers and how to overcome them) and clarification about how to record items that rely on estimation (e.g. alcohol units, fluid intake, urine output).

### The HIP Programme in Switzerland: The Gesundheitsfoerderungsprofil [GEPPsy].

Following publication of the development paper and at the invitation of Dr Chris Abderhalden, Director of the University Psychiatric Hospital, Bern, Switzerland the HIP Manual, HIP and the HIP Programme slides were translated into Swiss-German. I

delivered a series of workshops to Swiss mental health nurses through translators in August 2011. This was followed by a project to evaluate implementation of the Swiss-German version of the HIP, the Gesundheitsfoerderungsprofil [GEPPsy]. Sulin Bänziger analysed GEPPsy data for a cohort of 151 adult patients with SMI (96 from three community teams and 55 from the two inpatient wards serving the same catchment area) for her Master's thesis. The cohort was predominantly male (80%) and either had a diagnosis of schizophrenia 68% (n=103) or bipolar affective disorder 48% (n=32). Rates of comorbidity were similar to those seen in the Scottish HIP cohorts, with body mass index (68%), waist circumference (66%) and smoking (61%) the highest ranked risk items. Interestingly it appeared to be the items that required a blood test that were least likely to be completed on the GEPPsy, with 30 patients having no record for lipids and 17 none for glucose. Swiss mental health nurses and patients appeared to have less difficulty talking about sex; 5 patients had no record for the safe sex item and 1 for sexual satisfaction. A positive evaluation from surveys of patients (n=21), nurses (n=21), and home doctors (n=8) provided further evidence of acceptability, flexibility and (international) utility of the programme (Bänziger 2013).

## Chapter Summary

In this chapter opportunistic and pragmatic evaluations of data from implementation of the HIP (including a translated version) provided evidence of acceptability and utility in acute inpatient care in one hospital in Scotland and in secondary (inpatient and community) care in Switzerland. The inpatient cohort in Scotland had a worse physical comorbidity profile than community patients from the same area who were engaged in and attending a nurse-led clinic. Patterns of completion of the HIPs suggested barriers to having conversations about sex.

The evaluation work of the HIP inpatient cohort described in this chapter was disseminated by conference presentation in 2010:

White, J. 2010. Evaluation of the serious mental illness Health Improvement Profile [HIP]: The HIP 100. . *16th International Network for Psychiatric Nursing Research (NPNR) Conference: Collaborative research and partnership working 23rd September 2010.* . Wadham College, Oxford , Royal College of Nursing.

# Chapter Eight: Cluster Randomised Controlled Trial and Process Observation Methodology

The earlier chapters have established that physical comorbidity is a major cause of early mortality in serious mental illness and that the recommended annual health checks to address physical comorbidity in this population are not being routinely undertaken in any care setting. Although mental health nurses [MHNs] have a positive attitude towards a physical health role, deficits in knowledge and poor preparation are reported to impair their ability to deliver physical health care in practice. Training MHNs in physical health risk assessment could potentially address the physical health care deficit for SMI patients in contact with secondary (mental health) services.

A pre and post training evaluation established that MHNs gain knowledge from HIP training and are positive about their ability to use the HIP to support their future practice (White et al., 2013). The largest numbers of people with SMI in the UK are in community settings. A pilot and service evaluation of the HIP Programme demonstrated utility in 31 community patients (Shuel et al., 2010). Considerable physical comorbidity in this small sample of convenience was confirmed. Patients, nurses, psychiatrists and GPs reported they liked the HIP process and there was some evidence of appropriate intervention and health behaviour change following its use.

We do not know if receipt of an annual health check using the HIP in routine community mental health practice improves patient outcomes. It seems reasonable to progress from the pilot work to address the central research question:

> Does the HIP and the brief HIP training package for nurses [HIP Programme] result in improved health outcomes for patien

## Funding and approvals for a clinical trial

To achieve adequate grant funding for the clinical trial stage an application was made for a grant from the 9th competition for the National Institute for Health Research [NIHR] Research for Patient Benefit [RfPB] programme in the East of England. The application was developed with a group of collaborators led by Professor Richard Gray (as Chief Investigator), and included a medical statistician, health economist and public and patient involvement representatives. My role was to write and submit the grant application and respond to feedback from the research team and the NIHR peer reviewers (under supervision). I began the grant writing process in April 2009. The first attempt was shortlisted but unsuccessful, the second attempt was successful and the sponsor NHS Trust was awarded the grant of £249,159 in April 2011 to coincide with NHS approvals. My role as Project Lead was funded at 20% between April 2011 and April 2014. The trial

was prospectively registered with ISRCTN on 04/03/2011 (http://www.isrctn.com/ISRCTN41137900) and is included in the NIHR Portfolio database at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=8505.

Securing NHS ethics and governance approvals had to start before the outcome of the grant competition was known. Utilising knowledge and skills gained from an Integrated Research Approvals System (IRAS) course, under supervision and with collaboration from the research team, I constructed the 80 separate documents required for the approvals process and the Case Record Form [CRF]. This included a detailed research protocol and all participant information, consent forms, outcome measures and adaptation of existing validated measures. In collaboration with the Mental Health Research Network [MHRN], public and patient involvement representatives with SMI provided feedback on the structure of patient information and the feasibility of the design of the process observation phase when investigating the perceptions of patients. A second NHS site in Lincolnshire was engaged, as through my existing networks, as it was clear that we would be unlikely to achieve the required sample size from recruitment within the sponsor NHS Trust. The trial was granted ethical approval in December 2010 by the Cambridge East (previously Cambridge 4) Research Ethics Committee. NHS governance approvals for both Trusts were achieved in April 2011.

Once all approvals were achieved and the trial registration number (ISRCTN41137900) issued, the trial protocol was finalised by the Trial Steering Committee and I prepared it for submission to *Trials*.

## Design

The most robust method for answering the research question is a randomised controlled trial comparing health outcomes of patients treated by Community Mental Health Nurses [CMHNs] trained to use the HIP with those delivering routine treatment as usual. Patients of CMHNs are not independent of each other (one of the assumptions of standard statistical procedures) rather they are under the care of a nurse who is likely to provide similar care to all patients on their caseload. A design with the patient as the unit of randomisation would therefore risk contamination between groups. The community mental health team was rejected as a unit of randomisation for pragmatic reasons due to the small number of CMHNs in some teams and uncertainty about the ability to recruit from all available teams across all sites in such a large geographical region. In a cluster RCT that trained CMHNs in an adherence intervention with the CMHN as the unit of randomisation, there was no evidence of contamination between nurses in the same team (e.g. by sharing the intervention manual) (Gray et al., 2004). The CMHN was therefore selected as the unit of randomisation for this trial.

There were two parts to the study. In Part 1 a single-blind, parallel group randomised controlled trial design, clustered at the level of the CMHN was used. The study was planned in accordance with the Consolidated Standards of Reporting Trials [CONSORT] cluster trial extension reporting standards (Campbell et al., 2004). Knowledge of and attitude of the CMHNs towards a physical health role was to be investigated and compared between groups using a pre and post-test survey. It was planned to investigate any impact on cardiovascular risk modification using demographic data and data from the HIP in a pre and post 'within-treatment' group design. Part 2 of the study investigated the process and experience of the use of the HIP by patients and staff using semi-structured interviews and a case note audit. The retrospective nature of Part 2 meant that it had to take place after Part 1 had been completed.

**Main hypothesis**

The aim was to test the hypothesis that patients with SMI on the caseload of Community Mental Health Nurses [CMHNs] trained to use the HIP would have improved physical health related quality of life after a year compared to patients on the caseloads of nurses delivering usual care.

**Primary objective**

There have been no clinical trials to educate health professionals in physical health screening or intervention (including health advice) that have demonstrated a significant effect on physical health related quality of life in SMI patients (Hardy et al., 2011, Tosh et al., 2010, Tosh et al., 2014). Health related quality of life includes the physical, functional, social and emotional wellbeing domains unique to each individual that are effected by health and illness (Guyatt et al., 1993, Testa and Simonson, 1996). Physical health related quality of life attempts to quantify a person's subjective perceptions of their ability to cope in their physical health domain (Testa and Simonson, 1996).

The primary objective of the study was to determine the effects of the HIP Programme on patients' physical health-related quality of life over 12 months compared to treatment as usual (Objective 1). Objective measures of health gain were considered for this study (e.g. improvement in body mass index, blood cholesterol). However because the HIP addresses multiple health risks, multiple measures would have been required in both groups contaminating the TAU group with screening interventions so this approach was rejected.

**Secondary objectives**

The burden of CMHN training and additional screening and treatment of unmasked physical comorbidity in patients would incur additional service costs so an economic

evaluation assessed if the HIP Programme represented a cost-effective use of NHS resources (Objective 2). Little is known about the impact of physical health screening and care on the mental health of patients or training on nurse attitudes and knowledge. The impact of the HIP Programme on patients' mental health related quality of life (Objective 3) and CMHNs attitude towards and knowledge of physical health care (Objective 4) was evaluated. It was also planned to test the impact of the HIP Programme on modification of patients' cardiovascular risk (Objective 5), as cardiovascular risk represents the greatest physical health risk to mortality in this population. In addition the process of using the HIP, including patient and staff experience and impact on communication and care planning was explored (Objective 6).

## Outcome measures

The outcome measures used in the study are summarised in Tables 8.1and 8.3

**Table 0:1 Part 1 cluster RCT outcome measures**

| | HIP (baseline and 52 weeks*) | | TAU (baseline and 52 weeks*) | |
|---|---|---|---|---|
| | Patient subjects | Nurse subjects | Patient subjects | Nurse subjects |
| SF36v2 | X | | X | |
| EQ-5D | X | | X | |
| HRU-patient | X | | X | |
| HIP | X | | | |
| QRISK®2 | X | | | |
| HRU-Nurse | | X | | X |
| Adapted PHASe | | X | | X |

* = ± 14 days

**Table 0:2 Part 2 process observation outcome measures**

| | HIP | | | TAU | |
|---|---|---|---|---|---|
| | Patient subjects | | Nurse subjects | Patient subjects | Nurse subjects |
| Semi structured interview | X | | X | | |
| HIP Audit Form | HIP returned | HIP **not** returned | | | |
| | X | X | | X | |

CMHNs were randomised to either the HIP Programme or TAU Group to compare impact and cost effectiveness of the HIP Programme (Objectives 1-3).

The Medical Outcome Study (MOS) 36 Item Short Form Health Survey version 2 [SF-36v2] is a self-report multidimensional measure of health-related quality of life and wellbeing with well-established psychometric properties (Ware, 2007). The revised version of the SF36 has improvements in item wording and format and a 6-fold increase in the range of scores produced without increase in participant burden (Ware, 2004). It has been shown to have good sensitivity to change in outpatients with schizophrenia, uncommon among QoL measures (Russo et al., 1998). The scales of the SF-36v2 address eight health domains: physical functioning, role limitations due to physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. It allows the calculation of two summary scores: a physical component summary score [PCS] and a mental component summary score [MCS] both ranging from zero (poor health) to 100 (perfect health) (high = good). The PCS was selected as the main health quality of life outcome measure for the primary objective (Objective 1). As it was hypothesised that mental health-related quality of life may change as a result of the HIP Programme, this was evaluated using the MCS (Objective 3).

In line with a previous economic evaluations for patients with schizophrenia (Barton et al., 2009), levels of health care resource use [HRU] were captured via amended versions of the Client Service Receipt Inventory [CRSI] (Chisholm et al., 2000). Two HRU forms were designed for nurse and patient participants. The HRU-Patient monitored health professional visits, hospital admissions, medication etc. and was administered by a researcher blind to group allocation at baseline and at a 52 week follow-up visit. Nurses were asked to report the time taken to complete each HIP and any action taken as a result. using the HRU-Nurse.

The EuroQol 5 Dimensions Questionnaire [EQ-5D] is an established, standardised health-related quality of life instrument used extensively in clinical studies (The EuroQol Group, 1990). It provides a simple descriptive profile of each respondent and a single index value for their perceived current health status allowing a calculation of Quality Life Adjusted Years [QALYs]. It comprises five items covering the domains of mobility, self-care, usual activity, pain/discomfort, anxiety/depression and a visual analogue scale. The EQ-5D was selected for the effectiveness component of the economic analysis because it is cognitively simple and takes only a few minutes to complete, thus reducing participant burden. It was administered to all patient participants at baseline and at the 52 weeks post randomisation visit by a researcher.

The Mental Health Nurse Physical Health Attitude Scale [PHASe] is a 29-item questionnaire with established validity, designed to capture MHNs attitude towards their physical health care role (Robson and Haddad, 2010). The PHASe does not evaluate knowledge so it was adapted to include 20 physical health care multiple-choice questions [MCQs]. These questions were piloted and used to evaluate knowledge with forty-six nurses attending a physical health master class (White et al., 2013). All MHNs in the study were invited to complete the adapted PHASe online at baseline post randomisation and then again at the end of one year (Objective 4). Where the nurse failed to respond to two email reminders to complete the adapted PHASe online or they specifically requested it, they were sent a paper version in the post with a request to complete and return it in a stamped addressed envelope.

It was intended to measure cardiovascular risk using a 'within treatment' group design in the HIP Programme group patients at baseline and at 12 months to allow before-after change to be estimated (Objective 5). There are no cardiovascular risk prediction tools yet available specifically designed for an SMI population. QRISK®2 is a cardiovascular disease prediction algorithm providing an individualised estimate of risk using cholesterol, blood pressure and body mass index values, medical history and taking account of the independent contributions of ethnicity and social deprivation in the UK (by post code). Face validity, good discrimination and calibration of items has been established for QRISK®2 in the general population (Hippisley-Cox et al., 2008, Hippisley-Cox, 2009). It was intended to extract data from the HIP form and patient demographics for all subjects in the HIP Programme Group to enable a calculation of individual QRISK®2. Unfortunately the amount and poor quality of data entered into the HIP forms prevented this.

A process observation was conducted to assess the acceptability of the HIP Programme in the NHS (Objective 6). A retrospective documentation audit of the secondary care patient record compared details of documented physical health care and communication in a sub-sample of patient participants. Perceptions of the HIP were explored in a sample of patients and health professionals using a cross sectional semi-structured interview design. Outcome measures specifically designed for this process observation part of the study were used.

The HIP Audit form was designed by the Project Lead (the author) and piloted with four patients that also enabled researchers to become familiar with its use. No modifications were required after piloting. The HIP Audit form captured details of recorded physical health needs, care plan interventions, goals, review dates and interface communication (e.g. letters) from the secondary (mental health) care patient record. A researcher (MHN) administered the audit at the site with the largest number of participants.

Topic guides that included a series of open-ended questions and prompts guided the semi-structured face-to-face interviews with patients and nurses, and telephone interviews with psychiatrists. It was intended to interview GPs of the patient participants but none responded to the invitations. The Project Lead (me) and Process Observation Lead conducted face-to-face interviews and the Project Lead conducted the telephone interviews. Questions aimed to:

- Obtain insights into the patients' and health professionals' experiences of using the HIP
- Consider which elements of the HIP were perceived as being most and least helpful
- Explore participants' perceptions of the effect that they think the HIP (as opposed to TAU) has on them
- Uncover any potential barriers and blocks to using the HIP
- Explore how the HIP could be refined and enhanced.

## Sample size

### Part 1: Power Calculation

A sample size of 50 MHNs were sought (25 in the HIP and 25 in the TAU group), with 5 patients each resulting in an overall sample size of 250 patients (125 in the HIP and 125 in the TAU group). This was based on the following assumptions:

1. The data (scores on the outcome measures) are independent of each other. That is, scores of one participant are not systematically related to scores of the other participants.
2. The primary outcome of interest is improvement in community SMI patient's physical health related quality of life measured using the total Physical Component Score [PCS] of the SF36v2.
3. A two-tailed assumption is made for the (normal) distribution of PCS scores across the samples from participants in the two unrelated groups (HIP Programme and TAU).
4. A mean standard deviation of the PCS of 12 points was selected. This was identified from a reference group of 407 community patients with SMI in a trial of nurse led community care management in the US (Druss et al., 2010).
5. The level of significance for detecting an effect of the HIP Programme intervention was set at 5%.
6. A difference in means between intervention and TAU of 6 points in the PCS subscale is equivalent to an effect size of 5% (0.05).

7. As the intervention [HIP Programme] is directed at the CMHN (the cluster) with outcomes measured at the patient (individual) level, some within-cluster dependence was anticipated that required inflation in the sample size. An intraclass correlation coefficient [ICC] was calculated to determine the degree of within-cluster dependence (Donner, 1992). The degree of certainty that a true difference between groups (of at least 6 points) would be detected was 86% if an ICC of 0.1 is assumed, and nearly 80% if an ICC of 0.2 is assumed.
8. Applying an ICC of 0.2, using a 2-sided significance level of 0.05 requires randomisation of 200 patients.
9. The patient attrition rate in a previous cluster randomised controlled trial of a training intervention directed at CMHNs in the UK was 20% (Gray et al., 2004). Assuming a similar rate (50 patients) the randomisation of 5 patients per nurse at baseline was required.

All MHNs in the HIP and TAU groups were invited to participate in the online adapted PHASe at baseline and one year. All patients remaining the HIP Group at one year were intended to provide data for evaluation of any change in their QRISK®2 Scores.

**Part 2: Audit and semi-structured interview sample**

Thirty patients were purposefully selected from the HIP Programme Group (10 who received the HIP at baseline, 10 who did not receive the HIP at baseline) and 10 patients from the TAU Group to participate in the HIP Audit. All 30 patients were selected from the largest recruiting NHS site to make the best use of research staff time as this was the first site to complete Part 1 follow-up and data collection and un-blinding of research staff was required to facilitate data collection. This was therefore a sample of convenience.

It was intended to purposefully recruit from the HIP Group (on completion of Part 1) 10 patients to participate in the Patient Semi-structured Interviews, 10 nurses to participate in one-to-one interviews, 5 psychiatrists and 5 GPs to participate in the telephone interviews (30 in total). Small numbers of well-selected homogeneous interviewees (with adequate exposure to the phenomenon under study) can produce highly relevant information for analysis (Cleary et al., 2014). This qualitative part of the study was planned in accordance with the consolidated criteria for reporting qualitative research [COREQ] standards (Tong et al., 2007)

## Recruitment to Part 1

CMHNs were recruited from working age adult community, assertive outreach, rehabilitation, forensic and recovery teams serving the urban, coastal and rural

communities of the East of England that together serve a population of 4.3 million people. The sponsor NHS Trust expanded to include a neighbouring geographical area and this was approved as a third study site. A fourth NHS site was included after approaching the study team via the CLRN. Recruitment was undertaken by research assistants based in each of the four NHS sites, supported by the Project Lead and a Trial Coordinator. As Project Lead I managed all aspects of the study, supervised by the Chief Investigator.

It was intended to ask Team Leaders to nominate MHNs who met the inclusion criteria to the researcher who would then invite the MHN to participate in the trial by letter. Team Leaders reported they were too busy to perform this role so the Chief Investigator and/or Project Lead and researchers visited teams to present the study and distribute invitation packs. Recruitment events were also held at each of the sites with presentations from the Chief Investigator and/or Project Lead.

**Inclusion and exclusion criteria (CMHNs)**

CMHNs were included if they had been registered with the Nursing and Midwifery Council [NMC] for at least 6 months, were employed at Agenda for Change band 5-7 and had at least 5 patients on their caseload with a primary diagnosis of SMI. MHNs who responded positively to the invitation were briefly screened and excluded if they were still in preceptorship, about to go on maternity leave or pregnant. This was to try to make sure our nurse sample were likely to work with study patients across the 52 weeks of the trial.

Patient recruitment took place once a nurse was consented. It was intended to minimize self-selection bias by asking Team Leaders to list eligible patients on consented nurses' caseloads but this role was declined due to workload pressures. The researchers at site worked with each consented nurse to generate a list of eligible patients. Where the nurse thought that one of their patients who met the inclusion criteria diagnosis should be excluded, they were encouraged to discuss the reason for this with the Project Lead. Each patient was given a personal identification number [PID] to maintain anonymity.

**Inclusion and exclusion criteria (patients)**

Patients were included in the selection list if they were over 18 years of age, on the caseload of the consented CMHN and had a primary diagnosis of schizophrenia, schizoaffective disorder or bipolar disorder. Patients were excluded if they lacked the capacity to consent as documented by a heath professional in their case notes, had a serious or unstable medical condition (e.g. advanced cancer), were pregnant or 6 months post-partum or if participation in the trial may put the patient, nurse, team or researcher at increased risk or increased cost to the service to manage risk.

From the list of potentially eligible patients PIDs, 5 were selected at random using an algorithm designed by the Clinical Trials Research Unit [CTRU] at the University of East Anglia [UEA]. Selected patients were then approached and invited to participate by their nurse. If they expressed an interest they were seen by a researcher who provided detailed information about the study, checked their understanding and obtained their written informed consent to participate if they wished to proceed. If after completing a recruitment cycle five patients had not been recruited the process was repeated. The cycle was repeated until five patients had been recruited or all eligible patients on the nurse's caseload had been approached or six weeks had elapsed from the time the nurse's first patient consented. At this point, the nurse was randomized to receive either the HIP Programme or provide treatment as usual (TAU).

### Randomisation Method

Once the Trial Coordinator or Project Lead received notification of consent they allocated the CMHN a unique participant identification number [Nurse-PID]. All eligible patients on the CMHNs caseload were also allocated unique participant identification numbers by their nurse based on the Site ID, Nurse PID plus 001,002,003 etc. Patients from this list of PID numbers were randomly selected for invitation to the trial as described above. All Nurse and Patient PIDs were stored on the Trial Database at the CTRU. Only the Project Lead, Trial coordinator and database manager had access to the database to maintain blinding of researchers at site. Information about patients who declined, became no longer eligible (for example, due to a change in their capacity) or consented was entered in the database. Once either 5 patients had been consented per nurse or all eligible patients on the caseload had been exhausted or 6 weeks had elapsed from the first patient consent, the Project Lead or Trial Coordinator requested randomisation from CTRU.

The randomisation schedule, designed and held by the CTRU, used permuted blocks of random size to ensure equal allocation between clusters. With randomly permuted blocks, subjects are assigned to treatment in blocks to insure that equal numbers of subjects are assigned to each group. The Project Lead and Trial Coordinator or were informed of the result of randomisation by email and the Project Lead informed the CMHN of their group allocation by telephone. If the nurse was allocated to the HIP Programme Group information was exchanged about training. The opportunity was taken during this phone call to remind the nurse of the importance of maintaining the blinding of the researchers at site

### Recruitment to Part 2

This commenced once participants in the two NHS sites with the most participants had completed Part 1 and the researcher undertaking the audit at the largest site had

completed blinding tests. Sampling was undertaken by the Project Lead in a change to the published protocol, due to illness of the Process Observation Lead.

It was intended to purposefully sample patients for the retrospective case note audit from the pool of patients who remained in the study at Part 1 follow-up in the sponsor NHS site. However the relatively small numbers with completed HIPs and problems accessing teams and case notes due to service reconfiguration meant a pragmatic approach was taken. The researcher at site audited all available patients on a list generated by the Project Lead until the required sample size was achieved.

The Project Lead selected potential subjects for the semi-structured interviews from the two largest recruiting NHS sites using information from screening and the trial database. All patients in the HIP Group who remained in the study at Part 1 follow-up plus their study nurses, psychiatrists and GPs were invited to participate. The Project Lead sent an invitation pack directly to nurses, psychiatrists and GPs and to all eligible patients via their (study) nurse. Arrangements were made to interview every patient and health professional who responded positively to the invitation.

## Obtaining informed consent

A mental health service user group affiliated with the East of England Mental Health Research Network worked with the Project Lead to design the participant invitation letters, information sheets and consent forms used for patients in both parts of the study. All versions were approved by Cambridge East Research Ethics Committee and via NHS research governance at each site before use (please see Appendix 4 for the latest versions of the information sheets used the study). The study team were all experienced in exchanging information with patients with SMI and their carers and trained in taking consent in clinical trials. The same written information and contact with the research team was available for carers if required.

### Informed consent of CMHNs, Psychiatrists and GPs

Potential nurse participants who responded positively to the invitation to Part 1 received a Nurse Information Sheet Part 1 from a researcher who met with them and provide detailed explanation about the exact nature of the study. The researcher checked their understanding of the information and witnessed their written informed consent if they chose to proceed. Written information about the purpose of the PHASe (adapted) was available to read in a separate window before the CMHN decided if they wished to participate in the online survey or not, and in a cover letter if a postal questionnaire was sent. CMHNs were not required to sign a specific consent form for the survey as

completion and submission (or return) was considered implicit consent and this was included in the accompanying information.

In Part 2 potential nurse participants were sent an information pack with their invitation. If the response slip was returned indicating they were interested or they telephoned the Project lead or Process Observation Lead, detailed verbal information was exchanged and questions answered. Written individual informed consent was obtained just before the start of the interview for all participants who choose to attend in person and written informed consent was requested by fax from those who booked a telephone interview. At the start of each interview, ongoing process consent was verbally checked and recorded.

**Informed consent of patients**

A researcher contacted patients who responded positively to the initial invitation letter gven to them by their nurse. The researcher exchanged detailed written and verbal versions of the Patient Information Sheet Part 1 with them. Information about the evaluation of risk of physical health problems (including cardiovascular risk) is included in this information. The researcher checked their understanding of the information and witnessed their written informed consent if they chose to proceed.

Potential patient participants in the semi-structured interviews recieved detailed written versions of Patient Information Sheet Part 2 from the Project Lead or Process Observation Lead when invited to participate in this part of the study. Written individual informed consent was obtained just before the start of the one-to-one interview for all participants who agreed to an interview visit.

A copy of the signed Informed Consent form was given every participant. The original signed form was retained at the study site (for Part 1) or the central Trial Office at UEA (for Part 2). Where the participant was a patient of NHS Trust sites, an additional copy was filed in their Trust case record and their GP, Psychiatrist and Care-coordinator were informed in writing of their participation in the trial. At each data collection point involving an interview, ongoing verbal consent was sought and subjects reminded of their right to withdraw at any stage. Participants were also reminded that although data is anonymised, any disclosure that potentially puts them or others at risk would be communicated back to their CMHN and Care Co-ordinator (if this is a different person to the nurse).

## Description and core principles of Treatment as Usual

Community mental health teams are specialist, multi-disciplinary, multi agency teams that provide mental health assessments and interventions to individuals accessing mental health services. They prioritise interventions based on an assessment of need, risk and vulnerability, where complexity of care cannot be met within primary care. Services are

planned, delivered and reviewed in an integrated and co-ordinated way through the framework of the Care Programme Approach [CPA]. Working age adults with SMI under the care of these teams have a Care-Coordinator (usually a nurse, social worker or occupational therapist) who helps the individual identify their goals and package of care to achieve these. Core interventions will usually include assessment of risk of harm to self and others, assessment of substance misuse (including the delivery of basic harm minimisation and motivational interviewing interventions), medication management, risk and relapse prevention and planning, access to psychosocial support (e.g housing, employment, benefits), support to access primary care and other agencies (e.g. substance misuse services) and support for closely involved family and/or carer(s). All patient participants in the trial received treatment as usual.

## Description and core principles of the HIP Programme intervention

The core principles and elements of the education part of the intervention were described in detail in Chapter 6.

## Baseline and follow-up assessments

Assessments were completed by a site researcher blind to group allocation and took place at baseline and 52 weeks post-randomisation. Planning of 52-week appointments allowed for a two week window either side of the exact date appointments were due. Exact appointment dates may have fallen at a weekend, were not always convenient for patients or researchers and the window allowed at least one attempt at rearranging any missed or forgotten appointments.

Demographic information included gender, age, grade, caseload size, year of qualification, previous physical health care education (CMHNs), age, gender, ethnicity, post-code, primary diagnosis, recorded physical comorbidity diagnoses and medication (patients).

### Procedures to administer outcome measures and protect against sources of bias

Researchers were introduced to the protocol and trained to use the outcome measures by the Project Lead (me) and Chief Investigator using the Protocol, Case Record Form [CRF] and user manuals of the Sf36v2 and EQ-5D. Both measures are self-report, so training focussed on how to introduce them to participants and tests of inter-rater reliability were not required. The Project Lead was available to answer questions about the implementation of the protocol and support researchers throughout the trial via email and mobile and through the fortnightly Trial Management Group [TMG] meeting. Protocol violations and adverse events were recorded and reported to the sponsor and to the Trial Steering Committee [TSC].

The refusal of Team Leaders to be involved in patient selection from nurse's caseloads (as per protocol) meant the list of eligible patients identified had to be taken on trust and it is possible this introduced some selection bias. Where patients were identified and then reported as no longer eligible (e.g. due to a change in capacity or perception of increased risk) a conversation took place with the Project Lead and, sometimes if willing, the Team Leader was included. It was not possible to influence selection-bias regarding the intervention. Nurses were expected to complete HIPs with their study patients but did not always do so. When HIPs were not returned as expected, the Project Lead followed up with reminders by telephone and email. It was agreed that two attempts to contact the nurse by telephone and one email was an appropriate level of prompt.

The researchers at site who undertook patient baseline and follow-up outcome assessments did not have access to the database, randomisation process or email files and were blind to group allocation. All communication with participant nurses regarding the results of randomisation, their group allocation and training was from the Project Lead and Trial Coordinator who were not blinded. At every communication (telephone or email) participants were reminded about the importance of retaining blinding of the researchers. Nurses were asked to remind patient participants as the Project Lead and Trial Co-ordinator did not have or hold any personal patient data (e.g. names). There was one incident where a researcher at site was told the group allocation of a nurse. This was immediately reported and as patient follow-up had not yet taken place a different researcher was allocated to this task and blinding was maintained. Blinding tests were carried out once follow-up data collection was completed at each site. Researchers were asked to predict the group allocation of the patient participants at their sites and the results were compared with allocation and analysed.

Part 2 recruitment and data collection required staff who were aware of group allocation and took place (in the two largest sites) once Part 1 had ended. The Project Lead and Process Observation Lead undertook recruitment activity and the interviews. A researcher in the sponsor NHS site undertook the audits once all data collection and blinding tests had been completed for that site.

### Statistical analysis

Efficacy of the intervention was estimated by comparing the patient outcomes at 52 weeks between the two groups using mixed effects models including a random effect for the nurse to allow for the clustering. Our primary aim was to achieve an unbiased treatment comparison that took account of baseline factors, especially those factors that had some imbalance between treatment groups and could therefore potentially predict the outcome (Pocock et al., 2002). Models were fitted using Stata v12.1 and restricted log likelihood. Fifteen variables were identified *a priori* by the TSC as potential covariates i.e. that they

could possibly predict the outcome (Figure 8.1). We assessed the prognostic value of each of these in predicting the primary outcome SF36-PCS by fitting a mixed model for each with the potential covariate, baseline PCS as independent variables and follow up PCS as the dependent variable. It was agreed that any potential covariate with $P < 0.10$ would be included in models to obtain adjusted estimates.

**Figure 0:1 Potential covariates identified *a priori***

| Potential covariates (baseline scores) |
|---|
| NHS site |
| Type of Community Mental Health Team (e.g. assertive outreach) |
| Months on nurse's caseload |
| Nurse's knowledge score (adapted PHASe) |
| Nurse's attitude score (adapted PHASe) |
| Age (in years at consent) |
| Gender |
| Primary diagnosis |
| Living status |
| Smokes cigarettes |
| Diagnosed medical comorbidity |
| Total number of prescribed medications |
| Total number of prescribed antipsychotics |
| Prescribed a typical antipsychotic |
| Prescribed an atypical antipsychotic |

An intention to treat (ITT) analysis was performed. The ITT analysis set comprised all patients who were randomised, irrespective of their receipt of the intervention or not after randomisation. This is the main analysis and was used for the evaluation of all endpoints. Adjusted estimates in the ITT analysis were obtained by including all of the covariates with a prognostic value of $P = >0.1$ in a mixed model to estimate effect size.

Two per protocol analyses were planned. In per protocol analysis 1 [PP1] only patients who had a completed baseline HIP were included. In per protocol analysis 2 [PP2] only patients who had a HIP completed at baseline and at 52-week follow-up were included. A further per protocol analysis was necessary [PP Swap] due to a protocol violation. One nurse was randomised to the TAU group but assigned to the HIP training in error and therefore received the intervention. In the ITT analysis this nurse and 4 study patients was analysed in the TAU group, in the PP-Swap analysis they were analysed in the HIP Programme Group.

Descriptive statistics were used for the nurse and patient sample characteristics, counts and percentages for dichotomous variables (e.g. gender) and means and standard

deviations for continuous variables (e.g. age). Data from the adapted Mental Health Nurse Physical Health Attitude Scale [PHASe] and the supplementary twenty knowledge multiple-choice questions was compared between groups using student's *t*-tests to compare the mean scores and calculate 95% confidence intervals. All data were analysed using the Statistical Package for the Social Sciences [SPSS] (version 19; SPSS, Chicago, IL, USA). The planned analysis of QRISK®2 was not undertaken due to poor quality of HIP data.

In line with guidance by the National Institute of Health and Care Excellence [NICE], costs for the economic analysis were calculated from the perspective of the NHS and personal social services and encompassed those costs that were potentially related to the intervention (National Institute of Health and Care Excellence, 2008). We monitored the levels of resource use associated with completing the HIP (including those associated with recommended tests/investigations, changes in medication use and referrals to other services). For patients in both arms, we monitored visits to other health care professionals, admissions to hospital and medication usage. Appropriate unit costs were assigned to each of these items by the research team health economist. The EQ-5D -3L is a generic measure of health status designed to compare the benefits of different interventions (Brooks, 1996). The respondent is asked to indicate their health state by ticking a box against the most appropriate of three statements of level (representing no problems, some problems, severe problems) for five dimensions of health state (mobility, self-care, usual activities, pain, anxiety and depression). Respondents are then asked to place a cross on a vertical, visual analogue scale [EQ-5D VAS] with endpoints for the day of rating labelled 'Best imaginable health state' and 'Worst imaginable health state'. The dimensions of the EQ-5D were used to calculate quality-adjusted-life-years (QALYs) associated with both the intervention and TAU.

An economic model was constructed to estimate both the mean overall cost and mean overall effect associated with both the intervention and treatment as usual. If one of these options was shown to be less costly and more effective than the other then this would suggest that it 'dominates' the other, and represents a cost-effective use of scarce resources. Alternatively, the incremental cost-effectiveness ratio associated with the HIP will be estimated and assessed in relation to a range of cost-effectiveness thresholds e.g. a threshold of £20,000-£30,000 per QALY is recommended by NICE (NICE, 2008). The associated level of uncertainty was also characterised e.g. by estimating the cost-effectiveness acceptability curve [CEAC] for each intervention. Additionally, sensitivity analysis was undertaken to assess the robustness of conclusions to key assumptions.

Descriptive statistics were used to describe the nurse and patient sample characteristics for the nurses and patients participating in the interviews and the audit in the process

observation phase. All data collected in the HIP Audit Form represented dichotomous variables (i.e. the presence or absence of evidence in the patient record). These were compared between the three groups using a chi-square test. Data was analysed using SPSS (version 19; SPSS, Chicago, IL, USA).

### Thematic analysis of interview data

Interview data was analysed using thematic analysis and a constant comparative method. Thematic analysis involves searching across data sets for patterns of meaning (Braun and Clarke, 2006). The analysis method used to do this in this study was theoretical, rather than inductive because we were interested in the perceived drivers and barriers to the use of the HIP from the perspective of those patients and staff who had used it. The method described by Braun and Clark (2006) was used to analyse the data. All interview transcripts were read and re-read by a core group (the Project Lead (me), Chief Investigator and Process Observation Lead). The Process Observation Lead identified initial codes in the data and agreed these with the other two members of the group. NVivo Version 10 qualitative data analysis software (QSR International Pty Ltd, 2012) was then used to code all the transcript data and identify other possible theme groupings. Themes were agreed through a three-way process of discussion and by referring back to the transcripts until final themes were agreed, named and defined.

### Project schedule

A Gantt chart in Figure 8.2 summarises the project schedule for both parts of the study.

### Ethical and governance issues

Preparation and submission of all necessary documents through the integrated Research Approval Service [IRAS] was undertaken by the Project Lead (the author). The NHS Cambridge East Research Ethics Committee granted approval for the study in December 2010. NHS research governance approval was gained from the sponsor Trust in March 2011. Governance approval for the other NHS sites was granted in April 2011, December 2011 and February 2012 and for the former associated Primary Care Trusts in April 2013 Active recruitment to Part 1 of the study commenced on 04 April 2011. There were 8 minor amendments and 2 major (protocol) amendments during the study. The minor amendments to study documentation related to additional study sites, staff changes and an extension to the recruitment phase. The two major amendments were;

1) Due to a lower than expected recruitment of patients per nurse the number of nurses in each arm of the study was increased to 32 per arm. Assuming 4 patients per nurse (3 after drop out) this retains the power calculated previously, under the original assumptions and

2) a change to individual (rather than focus group) nurse interviews to facilitate recruitment in Part 2 and the introduction of three per protocol analyses. All amendments were approved by the Cambridge East Research Ethics Committee and managed by the Project Lead with the support of the Trial Coordinator.

Every effort was made to ensure that risks were minimised. Participants were provided with contact details of the research team and the local NHS Patient Advisory and Liaison Service [PALS]. The Project Lead, Trial Coordinator and all data collectors were experienced mental health researchers with training in Good Clinical Practice [GCP], NHS Research Governance and if appropriate, a current NHS Research Passport, Letter of Access or Honorary Research Contract. Researchers followed local Trust policies and procedures, including lone worker policies. Although data collected for the trial was anonymous, patients were reminded that any disclosure that potentially put them or others at risk (e.g. suicidal ideation, harm to self or others, or any identified medication risk) would be communicated back to their CMHN and/or care team. Similarly nurse participants were reminded that any disclosure or evidence of poor practice would be communicated back to their Team Leader. No complaints were received during the study. One patient withdrew consent because they found the data collection questions 'too intrusive' and another withdrew because they were unhappy with a medication review that was prompted when potential medication interactions were identified at baseline and reported to their care coordinator and psychiatrist.

CMHNs were asked to communicate details of any adverse events to participants and action taken to site researchers or the Trial Coordinator/Project Lead. All members of the research team followed the NHS research governance regulations and the National Research Ethics Service and standard operating procedures for safety reporting at all the NHS study sites. (Department of Health, 2005, Norfolk and Suffolk Foundation NHS Trust).

**Role of funder and sponsor**

This study was supported by a National Institute of Health Research [NIHR], Research for Patient Benefit grant. The sponsor Trust was Norfolk and Waveney Mental Health NHS Trust at the time of the award, but later merged with Suffolk Mental Health Partnerships NHS Trust on 1st April 2012 to form Norfolk and Suffolk NHS Foundation Trust.

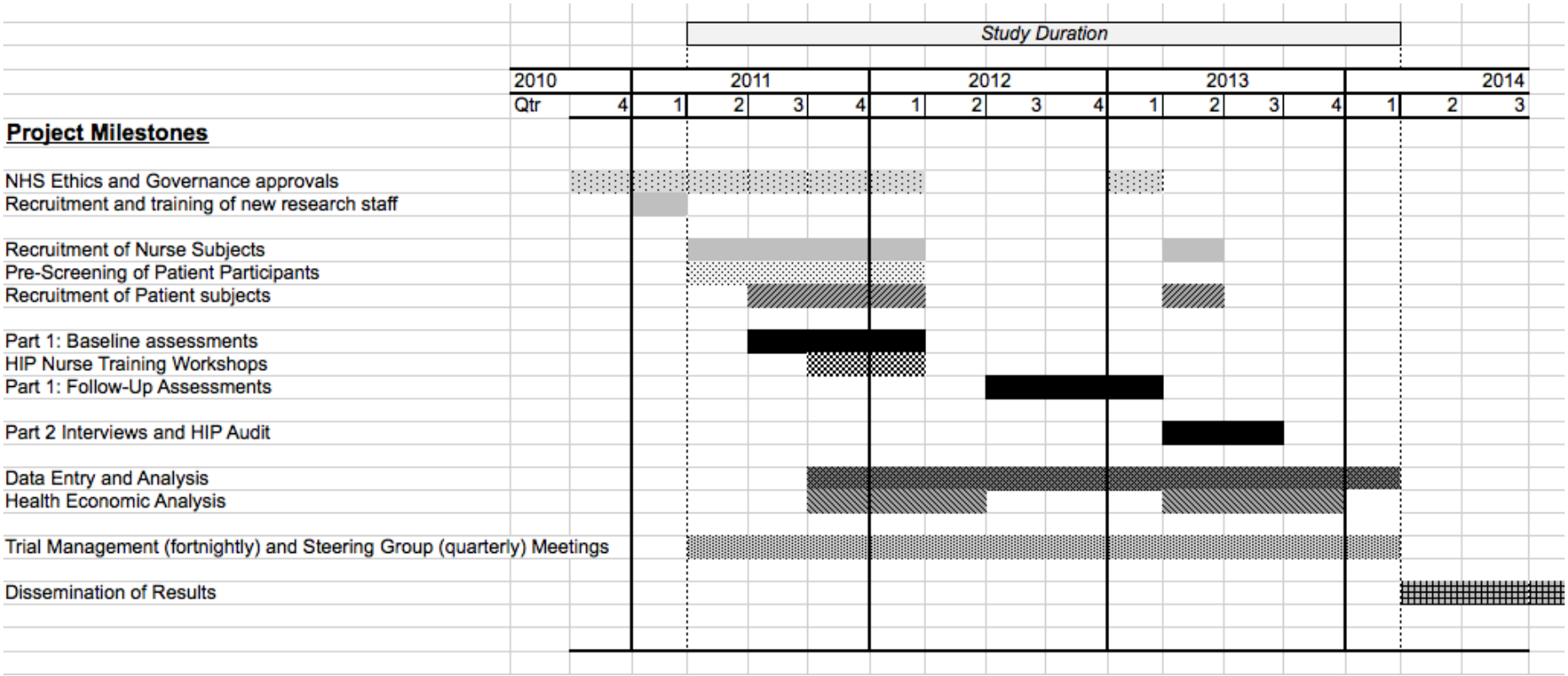
Annual and final reports were written and submitted to the NIHR, the sponsor, participating NHS sites and the Cambridge East Research Ethics Committee.

**Trial management and quality assurance**

The study was conducted in accordance with the NHS research governance framework and requirements of the National Research Ethics Service and standard operating

procedures of the sponsor NHS Trust. As Project Lead, I managed the study and was accountable to the Chief Investigator. I chaired a Trial Management Group [TMG] that included the Trial Coordinator and site researchers that met fortnightly by telephone conference. An independently chaired Trial Steering Committee [TSC] had the role of overseeing the conduct and progress of the trial. It met quarterly and included the Chief Investigator, all members of the research team, the sponsor representative, representatives from participating NHS sites and two public and patient involvement [PPI] representatives from the South Norfolk Care Commissioning Group. I met with PPI members before every TSC meeting to brief them on progress and make sure issues they wanted to raise were included in the main meeting.

**Figure 0:2 Project schedule**



The sponsor was responsible for evaluating compliance with regulations and standard operating procedures. Data was evaluated for compliance with the protocol and accuracy in relation to source documents by a team of auditors at the end of May 2012 and 2013. This included scrutiny of the Trial Master File, the Trial Site File and participant Case Records Forms at the University of East Anglia and the sponsor NHS site. The auditors reported that 'the standard of trial management and site files was excellent and a testament to the work of the trial coordinators and research assistants'.

## Chapter summary

To evaluate the success of the intervention, the HIP and the training package together [the HIP Programme], a clinical trial and additional process observation were planned. A single-blind, parallel group cluster randomised controlled trial design was adopted to test the effectiveness of the implementation of the HIP by CMHNs (the cluster) with SMI patients on their caseload. The primary end point of the study, a change in patients' physical related quality of life, was selected because it has meaning to patients, carers, practitioners and policy makers. The aim was to test the hypothesis that patients with SMI on the caseload of CMHNs trained to use the HIP would have improved physical health related quality of life after a year compared to patients on the caseloads of nurses delivering usual care. A health economic analysis was designed to provide information about the costs of disseminating this approach across the NHS. In addition to the primary evaluation of effectiveness and cost effectiveness, a pre and post survey design would test education (knowledge and attitude) outcomes in CMHNs in the HIP Programme group and a process observation phase would explore patient and practitioner experience of implementation using qualitative and audit data. The protocol was finalised by the TSC in March 2011 and the study took place between April 2011 and April 2013. The NHS research governance framework and requirements of the National Research Ethics Service and the sponsor NHS Trust were closely adhered to at all times. Pragmatic changes to the original finalised (and published) protocol to facilitate recruitment and to allow per protocol analyses were approved through these processes. These included recruitment from two additional NHS sites, an increase in the cluster size in the main trial and the replacement of nurse focus groups with individual semi structured interviews in the process observation phase.

The methodology described in this chapter was published in July 2011 as

White, J., Gray, R. J., Swift, L., Barton, G. R. & Jones, M. 2011. The serious mental illness health improvement profile [HIP]: study protocol for a cluster randomised controlled trial. *Trials,* 12**,** 167.

# Chapter Nine: Results of the HIP Cluster RCT (Part 1)

## Part 1 Participant Flow

Figure 9.1 shows the flow of nurses and patients through the trial. Out of 198 community mental health nurses [CMHNs] reported by the NHS sites to be working in their eligible community mental health teams [CMHTs], 131 did not respond to the invitation to participate (66%). Reasons are unknown due to the voluntary nature of recruitment following presentation to groups of staff. Sixty-seven CMHNs consented to take part but seven withdrew after consent but prior to randomisation due to a change in their circumstances. One nurse moved to work in a different service, one withdrew due to ill health, one stated the short-term nature of their role meant they could not complete annual health checks, two cited increased workload and two withdrew after all their eligible patients declined, citing workload reasons. Sixty (90%) of the original eligible CMHNs continued to work with researchers to recruit patients from their caseload and were randomised.

Six hundred and twelve patients were reported by their CMHN as eligible for inclusion in the study and entered the recruitment cycle process as described earlier. A third of eligible patients were not invited due to closure of the 6-week recruitment window before they could be approached. Of the remaining 402 patients, 52 (13%) were reported as no longer eligible by their nurse when selected for invitation so were not approached. Reasons cited were a change in capacity due to relapse (n=21), risk to mental health (n=20), risk to others (n=3), risk to self (n=2), and a new serious medical condition (n=2). One patient was discharged from the service, one moved out of area and another had disengaged from the team and did not respond to contact attempts. Despite research governance agreements, one eligible patient could not be invited because interpretation services were not available.

Of the 350 eligible patients who were invited to participate by their nurse, 173 (49%) provided written informed consent to enter the trial representing a mean of 2.6 patients per nurse (sd 1.93, 95% CI 1.73-2.10). We failed to recruit any patients at all from the caseloads of 16 consented nurses although 9 of these proceeded to randomisation.

The consented nurses were randomised between May 2011 and February 2012 to the HIP Programme intervention group (29 nurses, 90 patients) and the Treatment as Usual [TAU] group (31 nurses, 83 patients). In the intervention group 26 nurses received HIP training (corresponding to 84 patients). A protocol violation occurred due to an error in communicating the correct randomisation result. One nurse (and 4 study patients) who should have been in the TAU group received HIP Programme training.

### CMHN withdrawals and lost to follow up

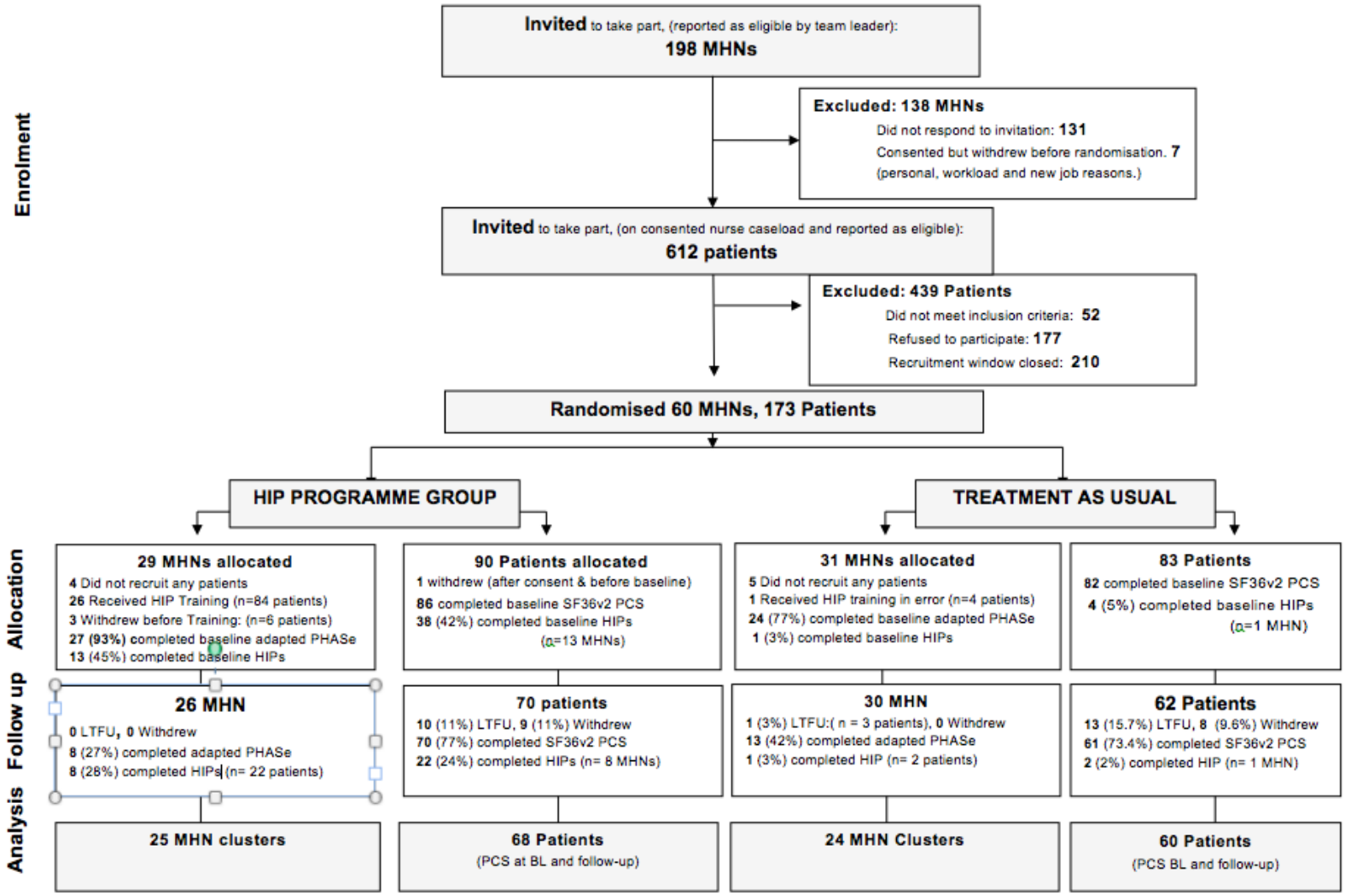
Of the 60 CMHNs who were randomised and entered the trial, 3 then withdrew their consent (5%). All three of these nurses were in the intervention group and withdrew after randomisation but before completing HIP Programme training (one nurse took up a position in a different service, the other two cited workload and personal reasons). Two of these nurses had patient participants who remained in the trial and were successfully followed-up. A CMHN in the TAU group completed baseline assessments but was lost to follow-up due to leaving to work for a different organisation. Their three consented patients remained in the trial and were successfully followed up.

### Patient withdrawals and lost to follow up

Of the 173 patients who entered the trial, 18 withdrew from the study, 10 from the intervention group and 8 from the TAU group. One patient withdrew after consent but before baseline data collection. Their primary diagnosis was confirmed as psychotic depression and not bipolar disorder as initially reported by their CMHN. The patient was given the option of continuing but chose to withdraw at that stage. Of the remaining 172 patients, 17 withdrew before follow up (10%). Five withdrawals occurred in the 12 months before follow-up, three patients gave no reason, one was annoyed that their medication had been reviewed as a result of being in the study and one had received a change in diagnosis so chose not to remain in the study at this point. Twelve withdrawals occurred when field researchers were attempting to arrange or begin the follow-up visit. Two thirds gave no reason (n=8). The remaining four provided different reasons; stress from life events, too unwell, that they did not like being interviewed as “the patient” and due to their discharge from the service.

Follow-up visits were arranged through the participating nurse (or current Care-Coordinator if the patient had moved to a different caseload during the intervening 12 months). An individual follow up window of 53 weeks ± 2 weeks from baseline data collection was imposed to maintain equity between participants across all sites. 23 (13%) patient participants either could not be contacted or were unable to arrange a data collection visit within their individual follow-up window: 10 from the intervention group and 13 from TAU.

**Figure 9:1 Participant flow through the trial**




MHN =Mental Health Nurse, PHASe = adapted Physical Health Attitude Survey, (adapted includes knowledge questions), LTFU = Lost to follow-up. SF36v2 PCS – Short Form 36 version 2 Physical Health Component, ITT = Intention to Treat

## Completed outcome measures

This section reports numbers with complete data available in the Case Record Form [CRF] for each of the measures used to analyse trial outcomes. Data collection visits took place with 168 patients at baseline and 132 patients at 53 week follow up. All nurse participants remaining in the trial were asked to complete the online adapted PHASe questionnaire at baseline and 53 week follow-up. Although the CONSORT diagram (Figure X) indicates the numbers of nurses who completed the adapted PHASe and completed HIPs with their study patients, it only indicates numbers completing the SF36v2 PCS for the primary outcome intention to treat analysis condition. The numbers of patients who had complete data for every measure at each time point are summarised in Table 9.1

**Table 9:1 Completed outcome measures (ITT condition):**

| | Patients with complete data at baseline | | Patients with complete data at follow-up | |
|---|---|---|---|---|
| **Group** | **HIP** | **TAU** | **HIP** | **TAU** |
| **Number of Patients** | n=90 | n=83 | n=70 | n=62 |
| **SF36v2 PCS and MCS** | 86 | 82 | 70 | 61 |
| **SF-6D**[a] | 82 | 77 | 64 | 57 |
| **EQ-5D-3L**[b] | 88 | 82 | 67 | 58 |
| **HRU-Patient** | 51 | 50 | 63 | 57 |
| **HIP** | 38 | 4[c] | 22 | 2[c] |
| **HRU-Nurse** | 26 | - | 10 | - |

| | Nurses with complete data at baseline | | Nurses with complete data at follow-up | |
|---|---|---|---|---|
| **Group** | **HIP** | **TAU** | **HIP** | **TAU** |
| | n = 29 | n=31 | n=26 | n=30 |
| **Adapted PHASe** | 27 | 24 | 8 | 13 |

[a] The SF-6D requires complete data for 11 questions on the SF36v2

[b] The EQ-5D-3L requires complete data from the EQ-5D and the EQ-5D Visual Analogue Scale

[c] Patients of the nurse who was incorrectly allocated to HIP Programme Training at randomisation

## Primary outcome

*1.Physical health related quality of life:*

Complete baseline SF-36v2 PCS and 53 week SF-36v2 PCS data were available from 128 (74%) patients. This represented 68 patients (under 25 nurses) in the intervention group and 60 patients (under 24 nurses) in the TAU group. Two patients in the intervention group and one in TAU were not included because their (matched) baseline PCS data was incomplete.

## Secondary outcomes

*2: Cost effectiveness of the HIP Programme:*

Quality of Life Years [QALYs]: there were two calculations of QALYs using the SF36v2 and the combined EQ-5D and EQ-5D Visual Analogue Scale data. SF-6D scores were calculated from the SF-36v2 patient data completed at the baseline and 53-week time points for 111 (64%) patients in total; 58 in the intervention group and 53 in the TAU group EQ-5D-3L data was available from the two time points for 123 (71%) patients; 66 in the intervention group and 57 in the TAU group.

Cost of the HIP Programme: Health Resource Use [HRU]-Patient data was available from both baseline and 53 week time points for 101 (58%) patients in total; 51 in the intervention group and 50 patients in TAU.

Complete data was captured to allow the cost of training to be calculated for all 26 CMHNs in the intervention group who received HIP Programme training. The CMHNs who completed HIPs with their patients were also asked to complete a HRU-Nurse form every time they used a HIP to capture the time taken to complete the process and estimated costs of action taken as a result. Where nurses returned a HIP but failed to return a corresponding HRU-Nurse form, a maximum of three emails or telephone messages were used to prompt them to do so. Twenty-six HRU-Nurse forms were returned that related to 62% of the 42 HIPs completed at baseline. Ten HRU-Nurse forms were returned at follow-up, corresponding to less than half (42%) of the 24 HIPs returned at this time point.

*3. Mental health related quality of life:*

Baseline and 53-week SF-36v2 MCS data was available from the same number of patients as the primary (PCS) outcome. One hundred and twenty-eight patients: 68 patients (under 25 nurses) in the intervention group and 60 patients (under 24 nurses) in the TAU group provided complete data for analysis.

*4. CMHNs attitude towards and knowledge of physical health care:*

Every consented nurse was invited via an automatic email to complete the measure online and then up to a maximum of two email prompts were sent to the nurse over a two-week

period if the Data Manager did not receive notification that it was completed. This provided the option for a paper version to be sent out if preferred. At baseline 51 (85%) CMHNs returned the adapted PHASe questionnaire. Twenty-seven CMHNs in the intervention group completed the measure and 24 from TAU. At the 53-week follow-up the response rate was 35% (n=21), representing 8 nurses in the intervention group and 13 in TAU. The results of the analysis of the nurse outcomes related to objective 4 are presented in the next chapter with the Part 2 (process observation) outcomes.

*5: Modification of cardiovascular risk (patients in the intervention group)*
As discussed in the methodology chapter, the calculation of this outcome required detailed data from the completed HIP forms. Of the forms that were returned, nurses had not completed them in a standardised way, particularly regarding blood test results for lipids and glucose. Consequently it was not possible to reliably calculate cardiovascular risk scores as planned.

*6: Acceptability of the HIP Programme in the NHS.*
The results related to this objective are presented in the next chapter as they relate to Part 2 of the study: the process observation that took place after Part 1 had been completed.

## Baseline characteristics of CMHNs (Part 1)

Table 9.2 lists the baseline characteristics of the CMHNs taking part in the study by group. There were no discernable differences between the groups.

## Baseline characteristics of patients (Part 1)

Table 9.3 lists the baseline characteristics of the patients by group. There were no discernable differences between the groups.

## Missing data

The 53-week primary outcome PCS was collected for 131 (76%) those patients who consented and entered the start of study. Three of these had no corresponding baseline measure so their data so could not be used when estimating the effect of the intervention. All four NHS sites differed significantly in the proportion of patients with missing values. Follow up rates for site one were 80% (76/95), site two, 82% (14/17) site three, 60% (29/48) and 92% (12/13) for site four. As the NHS site was not identified as a predictor of primary outcome, this was not a concern for the main analysis. In further bivariate analyses, no significant difference was found between patients with missing and non-missing PCS data with respect to any other variable in the patient baseline table (Table 9.3) or the nurse baseline table (Table 9.2).

There was an error in data collection at baseline for the first 25 patients at the largest NHS site because field researchers initially failed to include the last two pages of the HRU-Patient form in their printed CRFs. It was not feasible to go back and attempt to collect this missing data and the oversight was reported as a data risk to the Trial Steering Committee. The four questions omitted related to the calculation of NHS and personal and societal care [PSS] costs for the economic analysis. A further 37 patients from across all sites had missing or ambiguous HRU-Patient baseline data in one or more item on the form that was not resolved after raising a data query with the site. This meant that the estimate of baseline costs could not be calculated and used in the intention to treat [ITT] analysis as intended. All available HRU-Patient data was included in the sensitivity analyses.

## Sensitivity analysis

The original per protocol analysis plan was defined as the participant remaining in the same arm of the study at follow up as at randomisation (White et al., 2011). At the Trial Steering Committee meetings after data collection had ended it was agreed that three per protocol analyses should also be performed as there were three different conditions that determined if the patient had received some or all of the intervention as intended by their randomisation status:

*Per Protocol Swap*: This analysis took account of patients under the care of the single TAU group nurse who had been incorrectly assigned to the intervention arm at randomisation. It measured the intervention effect (adjusted for baseline score) between patients in the TAU group and intervention group, where patients of this nurse were allocated to the intervention arm in the analysis.

As with the primary ITT analysis, the evidence that a HIP had been completed was that a copy had been returned to the Trial Coordinator. We were unable to determine if there were cases where the patient's nurse had completed a HIP but forgot to return a copy to us. When prompting nurses in the HIP group to return HIPs and Nurse-HRUs two nurses reported they could not return copies to us because they could no longer access patients' records as a result of service reorganisation. As we could not corroborate these reports these patients were not included in the final two per protocol analyses.

*Per Protocol 1*: This only included intervention participants with documentation to prove they had completed a HIP at baseline in the analysis (n=42).

*Per Protocol 2:* This only included intervention participants with documentation to prove they completed a HIP at baseline *and* 12 month follow-up in the analysis. (n=24).

*Societal cost perspective*: The ITT analysis was repeated, where costs were estimated from a societal perspective.

*Multiple imputation*: Regression methods were used to predict cost and outcomes data based on their relationship with other covariates. As health resource use questionnaires were poorly completed at baseline, each cost component was disaggregated to achieve more accurate imputations. Disaggregated costs data was also imputed at 12-month follow-up, and EQ-5D and SF-6D values at each time point. Variables included in the imputation model were: nurse_ID, group, all baseline costs, all 12-month costs, intervention costs, baseline and 12-month EQ-5D, baseline and 12-month SF-6D, and baseline demographics, namely: age, sex, relationship status, smoking status, medical conditions, family history of cardiac disease, and years on nurse caseload. Imputation took place in five cycles, after which the total baseline costs, total 12-month costs; QALY (EQ-5D) and QALY (SF-6D) were generated. Imputed estimates were then pooled and calculated using Rubin's rules (Rubin, 1976). All multiple imputation was performed for incomplete cost and outcomes components at the patient level using the *mi impute* and *estimate* procedures in STATA 12 (Marchenko, 2009).

## Blinding and data checks

A check of 10% of all data entered into the trial database was undertaken by comparing it with source documentation in the CRF by one of the Trial Coordinators and one of the field researchers. The fidelity of blinding was tested in three field researchers who worked across two of the sites (1 and 2) at the end of baseline and at follow up data collection by asking them to predict the group allocation of participants from their site randomly selected by a Trial Coordinator. Tests indicated field researchers were no more likely than chance (50:50) to accurately predict patient group allocation.

**Table 9:2 Characteristics of CMHNs at baseline (Intention to Treat Analysis).**

| **Group** | | **HIP** | **TAU** |
|---|---|---|---|
| **Number of CMHNs** | | n=29 unless stated | n=31 unless stated |
| | | (%) or mean (sd) unless stated | |
| **NHS Site** | 1 | 13 (44.8%) | 14 (45.2%) |
| | 2 | 4 (13.8%) | 5 (16.1%) |
| | 3 | 7 (24.1%) | 10 (32.3%) |
| | 4 | 5 (17.2%) | 2 (6.5%) |
| **CMHT Type** | | | |
| | Recovery | 18 (62.1%) | 18 (58.1%) |
| | Assertive Outreach | 9 (31%) | 10 (32.3%) |
| | Rehabilitation | 1 (3.4%) | 0 (0%) |
| | Forensic | 1 (3.4%) | 3 (9.7%) |
| **Age** in years at consent | | 46.5(7.5) | 44.8 (8.9) |
| **Gender** | Female | 22 (75.9%) | 21 (67.7%) |
| **Ethnicity** | White British | 28 (96.6%) | 25 (83.3%) n = 30 |
| **Grade** | Band 5 | 0 (0%) | 1 (3.2%) |
| | Band 6 | 27 (93.1%) | 26 (83.9%) |
| | Band 7 | 2 (6.9%) | 4 (12.9%) |
| **Highest Academic level** | Certificate | 6 (20.7%) | 7 (22.6%) |
| | Diploma | 14(48.3%) | 12 (38.7%) |
| | Degree | 7 (24.1%) | 9 (29%) |
| | Masters | 2 (6.9%) | 3 (9.7%) |
| **MHN Experience** in years | | 16.5(9.6) | 14.16 (7.7) |
| **Time in post** | Less than 1 year | 3 (10.3%) | 3(9.7%) |
| | 1 – less than 5 years | 12(41.4%) | 11(35.5%) |
| | 5 – less than 10yrs | 10(34.5%) | 13(41.0%) |
| | 10 or more years | 4(12.9%) | 4(13.8%) |
| **Adult nursing qualification** | | 1 (3.4%) | 4 (12.9%) |
| **Knowledge**[a] MCQ score | | 9.7(2.6) n =27 | 8.8(2.2) n = 24 |
| **Attitudes**[a] PHASe score | | 32.1(5.5) n = 17 | 29.1(4.7) n=21 |

a. Identified as a potential covariate in patient analysis
MCQ = multiple-choice questionnaire
PHASe = Physical Health Attitude Scale.

## Table 9:3 Characteristics of patients at baseline (Intention to Treat Analysis).

| Group | | HIP | TAU |
|---|---|---|---|
| | | n=90 | n=83 |
| | | %(x/n) or mean (sd) unless stated | |
| **NHS site**[a] | 1 | 60.0% (54/90) | 49.4% (41/83) |
| | 2 | 10.0% (9/90) | 9.6% (8/83) |
| | 3 | 21.1% (19/90) | 34.9% (29/83) |
| | 4 | 8.9% (8/90) | 6.0% (5/83) |
| **CMHT**[c] **type**[a] | Recovery | 71.4%(60/84) | 68.3%(56/82) |
| **Months on caseload**[a] | median (min,max) | 24(3,168) n = 84 | 36(1,300) n = 77 |
| **Primary Diagnosis**[a] | Schizophrenia | 58.4% (52/89) | 69.9% (58/83) |
| | Schizoaffective disorder | 7.9% (7/89) | 7.2% (6/83) |
| | Bipolar Disorder | 33.7% (30/89 | 21.7% (18/83) |
| | Other | 0.0% (0/89) | 1.2% (1/83) |
| **Age**[a] in years at consent | | 47.6 (11.52) n = 87 | 45.1 (12.6) n = 83 |
| **Gender**[a] | Male | 52.3%(46/88) | 61.0%(50/82) |
| **Ethnicity** | White British | 88.9%(80/90) | 91.6%(76/83) |
| **Living status**[a] | Lives alone | 55.7%(49/88) | 57.8%(48/83) |
| **Relationship** | Single, divorced or widowed | 67.8%(59/87) | 70.7%(58/82) |
| **Smokes cigarettes**[a] | | 68.6%(59/86) | 9.3%(48/81) |
| **Medical Comorbidity Diagnosis**[a] | None<br>1-4 comorbidities<br>5 or more | 26.7%(23/86)<br>66.3%(57/86)<br>7.0%(6/86) | 22.9%(19/83)<br>69.9%(58/83)<br>7.2%(6/83) |
| **Total number of medications**[a] | median (min-max) | 4(0-18) | 4(0-20) |
| **Total number of antipsychotics**[a] | | | |
| | None | 3.6%(3/83) | 12.3%(10/81) |
| | One | 78.3%(65/83) | 74.1%(60/81) |
| | 2 or more | 18.1%(15/83) | 13.5%(11/81) |
| **Prescribed an atypical antipsychotic**[a] | | 75.9(63/83) | 60.5%(49/81) |
| **Prescribed a typical antipsychotic**[a] | | *28*.9%(24/83) | 33.3%(27/81) |
| **Family History of cardiovascular disease (CVD)** | | 23.5%(19/81) | 33.3%(25/75) |
| **Prescribed medicines for CVD**[b] | | 28.9%(24/83) | 27.2%(22/81) |
| **SF 36v2 PCS Baseline** | | 43.2 (11.0) n=86 | 45.1 (11.94) n=82 |
| **SF36v2 MCS Baseline** | | 39.2 (14.01) n = 86 | 36.92 (14.3) n = 82 |
| **EQ-5D VAS Baseline** | | 60.7 (20.8) n = 84 | 60.4 (19.1) n = 82 |
| **EQ-5D Baseline** | median (min,max) | 0.73 (-0.24,1.00) n=88 | 0.67 (-0.18,1.00) n=82 |

a = potential covariate,
b includes medications for diabetes, dyslipidaemia and hypertension
CMHT = Community Mental Health Team, PCS = Physical Component Scale, MCS = Mental Component Scale, VAS = Visual Analogue Scale

## Analysis of patient outcomes (Part 1)

*Intention to treat analyses*

A copy of the HIP was returned to the Trial Coordinator for 38 (42%) of intervention group patients at baseline and 22 (31%) at follow up

The effect of HIP compared to treatment as usual was estimated using mixed effects models including a random effect for nurse to allow for the clustering. Models were fitted using STATA v12.1 and restricted log likelihood. Fourteen variables (indicated in the baseline tables 9.2 and 9.3) were identified a priori as potential covariates. We assessed the prognostic value of each of these in predicting the primary outcome SF36v2-PCS by fitting a mixed model for each with the potential covariate, baseline PCS as independent variables and follow up PCS as the dependent variable. It was decided a priority that any potential covariate with $P < 0.10$ would be included in models to obtain adjusted estimates (Pocock et al., 2002). Number of medications ($P = 0.006$), taking one or more typical antipsychotic ($P = 0.077$) and the nurses MCQ knowledge score at baseline ($P =0.045$) all had $P < 0.10$. Adjusted estimates in the ITT analysis were obtained by including all of these in mixed model to estimate effect size and are included in Table 9.4.

The intervention effect (adjusted for baseline score) was not significant for the primary outcome (1.5 SF36v2 PCS points, 95% CI -1.5, 4.5 P=0.327, intra class correlation 0.036). No significant between group differences in secondary outcomes were found (Table 9.4). Further, no significant effect was found after adjustment for those potential covariates showing a prognostic relationship with the primary outcome (number of medications, one or more typical antipsychotics, nurse knowledge of physical health care).

None of the three per protocol analyses demonstrated a significant primary or secondary effect (Tables 9.5,9.6 and 9.7).

**Table 9:4 Estimated effects of HIP programme on primary and secondary outcomes at 12 months (Intention to Treat Analysis).**

| **Measure** | | **HIP** Mean (sd) | **TAU** Mean (sd) | **Effect**[b] (95% CI) (adjusted for baseline) P = | Intra class correlation | **Effect** (95% CI) (+adjusted for covariates) P= | Intra class correlation |
|---|---|---|---|---|---|---|---|
| SF36v2 | | | | | | | |
| n patients | | 68 | 60 | - | - | n =64,51 | |
| k nurses | | 25 | 24 | | | k=25,21 | |
| **SF36v2 PCS** | Baseline[a] | 43.36(10.97) | 44.07(10.82) | 1.50 (-1.50, 4.50) | 0.054 | 1.01(-2.0,4.0) | 0.036 |
| | 53 Weeks | 44.64(12.47) | 43.80(11.30) | P = 0.327 | | P=0.511 | |
| **SF36v2 MCS** | Baseline[a] | 40.26(13.08) | 37.89(13.94) | 1.38(-3.07,5.82) | 0.028 | 1.26(-3.0,5.5) | -0.035 |
| | 53 Weeks | 40.81(13.58) | 38.18(14.94) | P=0.543 | | p=0.561 | |
| EQ5D VAS | | | | | | | |
| n patients | | 63 | 61 | | | n=58,51 | |
| k nurses | | 25 | 24 | | | k = 25,21 | |
| **EQ5D VAS** | Baseline[a] | 60.08(20.18) | 60.25(19.36) | -2.30(-10.70,6.10) | 0.271[c] | -5.15 (-14.2,3.9) | 0.312 |
| | 53 Weeks | 55.57(24.61) | 58.11(20.35) | P=0.592 | | P=0.263 | |
| EQ5D | | | | | | | |
| n patients | | 66 | 57 | | | n=61,51 | |
| k nurses | | 24 | 24 | | | K=24,21 | |
| **EQ5D** | Baseline[a] | 0.632(0.306) | 0.607(0.330) | -0.01(-0.11,0.09) | 0.030 | -0.036(-0.134,0.063) | -0.012 |
| | 53 Weeks | 0.597(0.338) | 0.590(0.326) | P=0.870 | | p=0.478 | |

a = Effect of HIP versus Treatment as usual

b = Baseline mean is of those with follow up data

c = 95% CI for the ICC (0.05304,0.4639) Note: *estimated* ICCs *can* be negative.

**Table 9:5: Estimated effect of HIP programme on primary and secondary outcomes at 53 weeks (Per Protocol Swap Analysis)**

| **Measure** | | **HIP** Mean (sd) | **TAU** Mean (sd) | **Effect**[b] (95% CI) (adjusted for baseline) P = | Intra class correlation |
|---|---|---|---|---|---|
| SF36v2 | | | | | |
| n patients | | 67 | 61 | | |
| K nurses | | 25 | 24 | | |
| **SF36v2 PCS** | Baseline[a] | 42.5(11.5) | 45.0(10.1) | 0.51(-2.5,3.5) | 0.056 |
| | 53 Weeks | 43.5(12.9) | 45.0(10.8) | P=0.743 | |
| **SF36v2 MCS** | Baseline[a] | 40.2(12.9) | 38.0(14.1) | 1.98(-2.4,6.4) | 0.025 |
| | 53 Weeks | 41.1(13.7) | 37.9(14.7) | P=0.380 | |
| EQ5D VAS | | | | | |
| n patients | | 62 | 62 | | |
| k nurses | | 25 | 24 | | |
| **EQ5D VAS** | Baseline[a] | 59.5(20.4) | 60.79(19.1) | -0.26(-0.68,8.2) | 0.274 |
| | 53 Weeks | 56.2(24.2) | 59.5(20.4) | P=0.951 | |
| EQ5D | | | | | |
| N patients | | 65 | 58 | | |
| K nurses | | 24 | 24 | | |
| **EQ5D** | Baseline[a] | 0.621(0.3) | 0.618(0.33) | -0.01(-0.1,0.1) | 0.030 |
| | 53 Weeks | 0.588(0.3) | 0.600(0.32) | P=0.800 | |

a = Effect of HIP versus Treatment as usual

b = Baseline mean is of those with follow up data

**Table 9:6 Estimated effect of HIP Programme on primary and secondary outcomes at 53 Weeks (Per Protocol 1 Analysis)**

| **Measure** | | **HIP** Mean (sd) | **TAU** Mean (sd) | **Effect**[b] (95% CI) (adjusted for baseline) P = | Intra class correlation |
|---|---|---|---|---|---|
| SF36v2 | | | | | |
| n patients | | 32 | 61 | | |
| K nurses | | 15 | 24 | | |
| **SF36v2 PCS** | Baseline[a] | 44.2(12.6) | 45.0(10.1) | 1.01(-2.7,4.8) | -0.073 |
| | 53 Weeks | 45.5(12.6) | 45.0(10.8) | P=0.594 | |
| **SF36v2 MCS** | Baseline[a] | 39.5(14.4) | 38.0(14.1) | 2.32(-3.5,8.2) | 0.028 |
| | 53 Weeks | 40.9(15.0) | 37.9(14.7) | P=0.438 | |
| EQ5D VAS | | | | | |
| n patients | | 33 | 62 | | |
| k nurses | | 15 | 24 | | |
| **EQ5D VAS** | Baseline[a] | 60.9(23.1) | 60.8(19.1) | 6.09(-2.6,14.7) | 0.194 |
| | 53 Weeks | 63.5(20.2) | 57.5(20.9) | P=0.170 | |
| EQ5D | | | | | |
| N patients | | 34 | 58 | | |
| K nurses | | 15 | 24 | | |
| **EQ5D** | Baseline[a] | 0.654(0.310) | 0.619(0.330) | 0.000(-0.105,0.105) | -0.039 |
| | 53 Weeks | 0.622(0.354) | 0.600(0.315) | P=0.997 | |

a = Effect of HIP versus Treatment as usual

b = Baseline mean is of those with follow up data

**Table 9:7 Estimated effect of HIP Programme on primary and secondary outcomes at 53 Weeks (Per Protocol 2 Analysis)**

| **Measure** | | **HIP** Mean (sd) | **TAU** Mean (sd) | **Effect**[b] (95% CI) (adjusted for baseline) P = | Intra class correlation |
|---|---|---|---|---|---|
| SF36v2 | | | | | |
| n patients | | 20 | 61 | | |
| K nurses | | 8 | 24 | | |
| **SF36 PCS** | Baseline[a] | 43.8(11.8) | 45.0(10.1) | 2.87(-1.9,7.6) | 0.218 |
| | 53 Weeks | 46.6(11.3) | 45.0(10.8) | P=0.236 | |
| **SF36 MCS** | Baseline[a] | 43.3(14.6) | 38.0(14.1) | -0.76(-7.9,6.4) | 0.048 |
| | 53 Weeks | 39.7(15.6) | 37.9(14.7) | P=0.834 | |
| EQ5D VAS | | | | | |
| n patients | | 20 | 62 | | |
| k nurses | | 9 | 24 | | |
| **EQ5D VAS** | Baseline[a] | 67.1(23.2) | 60.8(19.1) | 5.84(-4.75,16.4) | 0.194 |
| | 53 Weeks | 66.5(18.6) | 57.5(20.9) | P=0.286 | |
| EQ5D | | | | | |
| N patients | | 21 | 58 | | |
| K nurses | | 9 | 24 | | |
| **EQ5D** | Baseline[a] | 0.700(0.316) | 0.619(0.330) | 0.022(-0.102,0.147) | 0.003 |
| | 53 Weeks | 0.672(0.326) | 0.600(0.315) | P=0.724 | |

a = Effect of HIP versus Treatment as usual
b = Baseline mean is of those with follow up data

## Health economic outcomes

A description of the resource use associated with the component parts of the intervention is provided in Table 9.8. Of the 90 participants allocated to the intervention arm, 42 were known to have received the HIP at baseline. Timings for HIP baseline completion were available for 26 of these 42 participants, where it was reported that the time taken to complete the HIP with the patient ranged from 30 minutes to 2 hours 10 minutes (mean = 61.92 minutes). For 25 of these 26 participants, it was reported that further non-patient contact time was required to complete the associated paperwork, where the time ranged between 15 minutes and 1.5 hours (mean = 31.40 minutes). In total, across the 26 participants, the mean time to conduct the baseline HIP was thereby 92.12 minutes (range 45 minutes to 3.5 hours). On the assumption that half of the contacts took place at the nurses' workplace (cost of £40 per hour) and half took place in the patients' home (cost of £70 per hour), then this would equate to a mean cost of £84.44 across the 26 participants. This mean baseline HIP cost was also assigned to the 16 participants who were known to have received the HIP but failed to complete the nurse questionnaire. The other 48 participants in the intervention arm were assumed not to have received the HIP at baseline and hence no cost for the completion of the HIP was assigned to them. Together, this meant that the mean cost of conducting the HIP at baseline was £39.40.

### Table 9:8 Intervention costs

| Component part | Resources costed, participant costing | Mean cost (£ per participant) |
|---|---|---|
| Training | Updating the HIP manual (2 trainer days), preparation of training materials (2 trainer days), preparation for the sessions, including agreement of time and venue (4 trainer hours), travel time (25 trainer hours, 6 trainee hours), travel cost (883 trainer miles and 212 trainee miles @45p per mile), and session time (49 trainer and trainer hours). Equally apportioned across N=90 participants. | 110.32 |
| HIP consultations | 42 baseline (mean time = 92.12 minutes) and 23 follow-up (12 month) consultations (mean time = 54.50 minutes) | 52.17 |
| **Total** | | **162.50** |

### Table 9:9 Mean levels of resource use per participant and associated costs

| | Mean levels of resource use (n respondents) | | Mean cost (£) | |
|---|---|---|---|---|
| | 12 month follow-up | | 12 month follow-up | |
| **Item** | **HIP group** | **Control** | **HIP group** | **Control** |
| Health professional visits | 36.1 (67) | 48.3 (61) | £1,690.01 | £2,125.80 |
| Hospital admissions | 0.23 (65) | 0.36 (61) | | |
| Total number of days in hospital | 6.4 | 5.2 | £2,272.97 | £1,989.46 |
| Other healthcare services | 1.7 (65) | 5.7 (61) | £70.58 | £249.65 |
| Medication prescriptions | 59.8 (64) | 62.4 (59) | £1282.09 | £1083.02 |
| Tests and investigations | 1.5 (63) | 1.7 (60) | £39.13 | £59.76 |
| Total other NHS and PSS costs | (59) | (58) | £5,629.79 | £5,710.07 |
| **Total NHS and PSS costs** | **(59)** | **(58)** | **£5,796.08** | **£5,710.07** |
| Hours of care (per week) - paid | 3.3 (63) | 2.1 (57) | £1,050.17 | £719.42 |
| Hours of care (per week) - unpaid | 7.0 (63) | 3.6 (57) | £3,246.11 | £3,274.07 |
| Total care costs | (63) | (57) | £4,296.29 | £3,993.49 |
| **Total societal costs** | **(57)** | **(54)** | **£10,293.09** | **£9,854.67** |

At 12-month follow-up, 24 of the 90 participants allocated to the intervention arm were known to have received the HIP. Timings for HIP completion were available for 10 of these 24 – on average, completion of the HIP with the patient took 44 minutes (range 20 to 60 minutes), 4 of the 10 reported additional non-contact time with a mean of 26.25 (range 15 to 30 minutes). In total, across the 10 participants, the mean time to conduct the follow-up HIP was thereby 54.50 minutes (range 10 minutes to 70 minutes hours), which equates to a cost of £49.96 (at a cost of £55 per hour). This mean follow-up HIP cost was also assigned to the other 14 participants who were known to have received the HIP. The other 66 participants in the intervention arm were assumed not to have received the HIP at follow-up and hence no cost for the completion of the HIP was assigned to them. Overall, the mean cost of completing the HIP at follow-up was £12.66. When these baseline and 12 month follow-up HIP completion costs were summed together the mean cost was estimated to be £52.07 (56.80 minutes). To account for the 4 HIPs at baseline and 2 at follow-up conducted by the nurse who was trained in error no costs were assigned to these contacts in the base-case but the sensitivity analyses incorporated them.

When the HIP completion costs are added to per participant total training costs the total intervention cost was estimated to be £162.50 per participant (range £110.32 - £302.82). One of the reasons that training costs are so high is that nurses found it difficult to take the time away from clinical activities in order to travel to training. As such, training was largely delivered on a one-to-one basis at the team base.

Overall, the mean (per participant) total other NHS and personal social services [PSS] costs was £5,796 for intervention arm participants and £5,710 for control arm participants. When carer costs we included, the total societal costs were £10,293 and £9,8545, respectively (Table 9.9). The main unit costs attached to the various resource use is summarised in a table in Appendix 7.

The mean baseline and follow-up utility scores (for both the EQ-5D and SF-6D) are shown in Tables 9.10 and 9.11, along with the QALY score over the 12-month follow-up period.

**Table 9:10 estimates of the mean utility and mean QALY scores based on the EQ-5D**

| | Group | Baseline score | 12 month follow-up score | Unadjusted Difference | 12 month QALY score |
|---|---|---|---|---|---|
| ITT | HIP | 0.635 (N=88) | 0.600 (N=67) | –0.035 (N=66) | 0.614 (N=66) |
| | Control | 0.611 (N=82) | 0.592 (N=58) | –0.017 (N=57) | 0.598 (N=57) |

**Table 9:11 Estimates of the mean utility and mean QALY scores based on the SF-6D**

| | Group | Baseline score | 12 month follow-up score | Unadjusted Difference | 12 month QALY score |
|---|---|---|---|---|---|
| ITT | HIP | 0.580 (N=82) | 0.599 (N=64) | 0.008 (N=58) | 0.587 (N=58) |
| | Control | 0.580 (N=77) | 0.588 (N=57) | 0.011 (N=53) | 0.588 (N=53) |

*Intention to treat analyses*

Estimates for the mean incremental cost and mean incremental effect are given in Tables 9.12 (EQ-5D) and 9.13 (SF-6D). It can be seen that these are based on data from 64.7% of participants for the EQ-5D and 58.4% for the SF-6D. In both analyses it was estimated that there was no significant difference between the groups with regard to either costs, though the mean total NHS and PSS cost was estimated to be slightly lower in the intervention arm. For outcomes, the mean QALY score for the intervention group was estimated to be slightly higher for the SF-6D, but slightly lower for the EQ-5D, though again neither of these differences were significant. For both analyses, the net benefit figures were positive at the £20,000 per QALY mark. However, there was a large uncertainty associated with this decision as, at this value of λ, the CEAC estimated the probability that the HIP was cost-effective to be 59.4% for the EQ-5D and 58.1% for the SF-6D (at £30,000 per QALY the figures were 56.7% and 58.3% respectively) i.e. there was estimated to be a >40% chance of making the wrong decision, with regard to cost-effectiveness, if we chose to implement the HIP Programme intervention.

*Sensitivity analysis*

Results for the societal cost perspective, the multiple imputation analysis and per protocol analyses are also shown in Tables 9.12 and 9.13. The estimated mean incremental cost and mean incremental effect did not change appreciably in any of sensitivity analyses that were performed, as it can be seen that the confidence intervals surrounding both estimates always encompassed zero.

**Table 9:12 Estimates of the incremental cost, incremental effect (based on the EQ-5D) and incremental cost-effectiveness ratio based on regression analysis**

| Analysis (N in each group) | Incremental cost* (£) (95% CI) | Incremental QALY | Incremental cost-effectiveness ratio (ICER) / Net monetary benefit (NMB) (£) |
|---|---|---|---|
| Base-case (58 HIP, 54 C) | –355.20 (–3,213.65 to 2,503.26) | –0.008 (–0.059 to 0.044) | NMB = 203.72 |
| SA: Societal cost perspective (58 HIP, 54 C) | –228.63 (–3837.71 to 4294.97) | –0.008 (–0.061 to 0.045) | NMB = 68.62 |
| SA: Multiple imputation (90 HIP, 83 C) | –372.48 (–3121.10 to 2376.14) | –0.011 (–0.074 to 0.052) | NMB = 152.48 |
| SA: Per protocol swap (trained) (57 HIP, 57 C) | 547.48 (2211.12 to 3306.09) | –0.009 (–0.061 to 0.043) | Dominated |
| SA: Per protocol 1 (Baseline HIP) (29 HIP, 55 C) | –341.18 (–3,213.65 to 2,503.26) | 0.016 (–0.041 to 0.074) | Dominant |
| SA: Per protocol 2 (Baseline and follow-up HIP) (19 HIP, 55 C) | –49.87 (–4140.85 to 4041.10) | 0.016 (–0.042 to 0.074) | Dominant |

*Based on total NHS and PSS costs, unless otherwise stated; 95% CI = 95% confidence interval; SA=Sensitivity analysis

**Table 9:13 Estimates of the incremental cost, incremental effect (based on the SF-6D) and incremental cost-effectiveness ratio based on regression analysis**

| Analysis (N in each group) | Incremental cost* (£) (95% CI) | Incremental QALY | Incremental cost-effectiveness ratio (ICER) / Net monetary benefit (NMB) (£) |
|---|---|---|---|
| Base-case (51 HIP, 50 C) | –230.81 (–3,188.49 to 2,726.88) | 0.001 (–0.024 to 0.026) | NMB = 256.65 |
| SA: Societal cost perspective (51 HIP, 50 C) | –65.62 (–4,169.51 to 4,038.27) | 0.001 (–0.026 to 0.027) | Dominant |
| SA: Multiple imputation (90 HIP, 83 C) | –372.48 (–3121.10 to 2376.14) | 0.011 (–0.015 to 0.037) | Dominant |
| SA: Per protocol swap (trained) (51 HIP, 50 C) | 738.74 (–2,119.33 to 3,596.81) | –0.003 (–0.028 to 0.022) | Dominated |
| SA: Per protocol 1 (Baseline HIP) (26 HIP, 51 C) | 459.15 (–2,882.28 to 3,800.59) | 0.008 (–0.026 to 0.041) | ICER = 57,938.62 |
| SA: Per protocol 2 (Baseline and follow-up HIP) (17 HIP, 51 C) | 866.32 (–3,433.39 to 5,166.02) | 0.006 (–0.031 to 0.044) | ICER = 135,262.64 |

*Based on total NHS and PSS costs, unless otherwise stated; 95% CI = 95% confidence interval; SA=Sensitivity analysis

## Adverse events (patients)

Three patient deaths were reported to the research team during the course of the study although two of these occurred after follow-up data collection in Part 1 was complete but before the study site had closed. Two deaths were in the TAU group and one in the HIP group. A senior medical clinician investigated all adverse events according to the sponsor's Standard Operating Procedures and requirements of the Research Ethics Committee. All three deaths were attributed to cardiovascular disease and none were considered related to participation in the trial (Table 9.14). All adverse events that met the definition of a serious adverse event [SAE] are summarised in Table 9.14. There were five adverse events that did not meet this criteria but were reported to the NHS research manager at each site and to the trial sponsor. These included potential medication interactions observed when collecting medication data that were reported back to the patient's psychiatrist and GP (n=2 patients), day surgery (n=2, in the same patient) and a report of pain and dizziness from one patient to that was immediately communicated to their nurse.

**Table 9:14 Serious Adverse Events reported in the study (patient participants)**

| Group | HIP | TAU |
|---|---|---|
| Number of deaths [a] | 1 | 2 |
| Number of episodes of self-harm | 1 | 0 |
| Number of psychiatric admissions | 11 | 11 |
| Number of general hospital admissions | 3 | 7 |
| Number of other serious medical conditions | 1 | 1 |
| **Total SAEs** | **17** | **21** |

a. One of the deaths in each group was reported after the follow-up data collection period for that patient had ended but before the close of study site.

## Chapter summary

In this chapter I have reported the results of the HIP Cluster RCT. There was no significant difference between the HIP Programme and Treatment as Usual groups on the primary and secondary outcome measures in patient participants. This null effect remained after adjustment was made for those potential covariates showing a prognostic relationship with the primary outcome. A variety of sensitivity analyses that took account of missing data and deviations from the protocol also found no differences between the

groups. Implementation of the HIP programme was not estimated to result in a significant difference in either physical or mental health related quality of life, cost or QALYs.

# Chapter Ten: Nurse outcomes (Part 1) and results of the process observation (Part 2)

## Nurse outcomes in the Cluster RCT (Part 1)

### Nurse attitude and knowledge

The adapted Physical Health Attitude Survey [PHASe] was completed by 85% (51/60) nurse sample at baseline but only 37.5% (21/56) of the nurses who remained in the study at follow up (Appendix 5). The small number of nurses who completed both the baseline and follow up questionnaire in each of the study groups meant it was not possible to compare mean scores and subscales between groups, as intended in the protocol.

### Characteristics of nurses who returned a HIP

The characteristics of the nurses in the HIP Group who did and did not return a copy of a completed HIP to the study team during Part 1 of the study are summarised in Table 10.1. Nurses not returning a HIP appeared more likely to be male and working in an assertive outreach team at baseline, than in the other types of community mental health teams represented in the sample. There were no other discernible differences between groups.

### Adverse Events (nurses)

We collected data about nurses who went off on long term sick leave during the trial so we were aware not to contact them to attempt to follow them up while they were unwell. The member of staff involved either communicated this information directly to the research team or a message came from their Team Leader. In total three nurses were reported to the team to be on long-term sick leave during the trial period after randomisation and all three of these were in the HIP Group. One became unwell between randomisation and HIP Programme Training, so did not receive training or complete the baseline adapted PHASe. Two returned from leave before the end of the study at their site so were included in follow-up data collection. The remaining nurse returned just after their individual follow-up window had closed but requested and was included in Part 2. The trial NHS sponsor's Standard Operating Procedure for Reporting of Adverse Events was adhered to and it was determined that none of the Adverse Events were related to the trial. There were no other reports of adverse events regarding nurses in the trial.

## Table 10:1 Characteristics of nurses in the HIP Group who did or did not return a HIP

| Group | | HIP returned [a] | HIP not returned | Total HIP Group[a] |
|---|---|---|---|---|
| **Number of CMHNs** | | n=15 unless stated | n=12 unless stated | n=30 unless stated |
| | | X (%) or mean (sd) | X (%) or mean (sd) | X (%) or mean (sd) |
| **NHS Site** | 1 | 8 (5.3%) | 4 (33.3%) | 13 (44.3%) |
| | 2 | 3 (20%) | 1 (8.3%) | 4 (13.3%) |
| | 3 | 3 (20%) | 3 (25%) | 8 (26.7%) |
| | 4 | 1 (6.7%) | 4 (33.3%) | 5 (16.7%) |
| **CMHT Type** | | | | |
| | Recovery | 12 (80%) | 4 (33.3%) | 19 (63.3%) |
| | Assertive Outreach | 1 (6.7%) | 8 (66.7%) | 9 (30%) |
| | Rehabilitation | 1 (6.7%) | 0 (0%) | 1 (3.3%) |
| | Forensic | 1 (6.7%) | 0 (0%) | 1 (3.3%) |
| **Age** in years at consent | | 45.9 (9.2) | 48.3 (5.7) | 46.9 (7.7) |
| **Gender** | Female | 13 (86.7%) | 7 (58.3%) | 23 (76.7%) |
| **Ethnicity** | White British | 14 (93.3%) | 12 (100%) | 29 (96.7%) |
| **Grade** | Band 5 | 0 (0%) | 0 (0%) | 0 (0%) |
| | Band 6 | 15 (100%) | 12 (100%) | 28 (93.3%) |
| | Band 7 | 0 (0%) | 0 (0%) | 2 (6.7%) |
| **Highest Academic level** | Certificate | 1 (6.7%) | 4 (33.3%) | 6 (20%) |
| | Diploma | 8 (53.3%) | 5 (41.7%) | 14 (46.7%) |
| | Degree | 5 (33.3%) | 2 (16.7%) | 7 (23.3%) |
| | Masters | 0 (0%) | 1 (8.3%) | 2 (6.7%) |
| **MHN Experience** in years | | 13.4 (7.4) | 18.6 (10.4) | 16.5 (9.6) |
| **Time in post** | Less than 1 year | 2 (13.3%) | 1 (8.3%) | 3 (10%) |
| | 1 – less than 5 years | 5 (33.3%) | 5 (41.7%) | 12 (40%) |
| | 5 – less than 10yrs | 7 (46.7%) | 4 (33.3%) | 11 (36.7%) |
| | 10 or more years | 1 (6.7%) | 2 (16.7%) | 4 (13.3%) |
| **Adult nursing qualification** | | 1 (6.7%) | 0 (0%) | 1 (3.4%) |
| **Knowledge** MCQ (baseline) | | 9.9 (3.0) n=14 | 9.5 (2.2) n=11 | 9.7 (2.6) n=27 |
| **Attitude** PHASe (baseline) | | 28.7 (8.1) n=10 | 34 (3.1) n=8 | 31.1 (6.8) n= 18 |
| **Confidence** PHASe (baseline) | | 15.1 (7.2) n=10 | 15 (5.1) n=8 | 15.1 (6.2) n=18 |
| **Barriers** PHASe (baseline) | | 30.8 (4.5) n=10 | 29.9 (4.4) n=8 | 30.4 (4.4) n=18 |
| **Attitude towards smoking** PHASe (baseline) | | 18.6 (6.6) n=10 | 19.1 (2.2) n=8 | 18.8 (5.0) n=18 |

a = includes the nurse who was allocated to TAU but received HIP Programme training in error.
**HIP returned** represents all nurses in HIP group who completed at least one HIP with at least one of their study patients.
**HIP not returned** represents all nurses in HIP group who received HIP training but did not complete a HIP with any of their study patients (three nurses withdrew before training).
**Total HIP Group** represents all nurses who were randomised to receive HIP Programme training
MCQ = multiple-choice questionnaire
PHASe = Physical Health Attitude Scale.

## Results of the Process Observation (Part 2)

The results of Part 2 of the study relate to the final secondary outcome (6); *Acceptability of the HIP Programme in the NHS.*

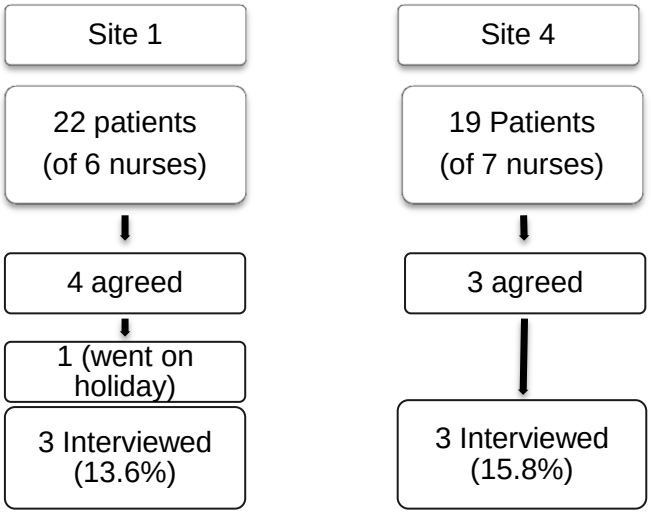
### Recruitment to interviews

Postal invitations were sent out to all HIP Group nurses from the two largest NHS study sites who remained in the trial at follow-up in Part 1 of the study (N=15). Of these, five nurses agreed to participate in an interview, two from site 1 and three from site 4. Only two replied with reasons for not wanting to participate and both stated this was because they were too busy with their clinical work. The remaining 8 nurses did not return a response slip so their reasons are unknown. Four interviews were conducted face to face as per protocol but one was undertaken by telephone following a specific request from the nurse. All interviews were recorded and transcribed verbatim.

Patient recruitment is summarised in Figure 10.1. The patient participants of the fifteen nurses invited to Part 2 who had been successfully followed up in Part 1 were identified by the Project Lead (n=55). The study nurse (or a study nurse in the same team if the nurse had withdrawn) was asked to hand deliver invitations to identified patients. At site 1 a pragmatic subsample of 6 nurses were selected (who worked nearest to the University) and asked to pass on invitations to 22 study patients. Of these, 4 initially agreed and 13.6% (n=3) were interviewed .Two of these three patients had records of the HIP being returned to the study team during Part 1. At site 4 there were a total of 19 patients remaining in the HIP Group after Part 1 and invitation packs were distributed to their 7 study nurses. 15.8% (n=3) patients responded to the invitations and agreed to be interviewed. Only one of these three patients had records of the HIP being returned to the study team during Part 1.

Invitations were sent by post to the consultant psychiatrists and GPs of all 41 patients who had been sent Part 2 invitation packs. There was a certain amount of overlap between these clinicians in terms of their caseloads so that 12 psychiatrists and 28 GPs in total were invited. All interviews were conducted by the Process Observation Lead (at site 1) and myself (at site 4).

**Figure 10:1 Patient recruitment to part 2 interviews**




Field notes were taken in the patient interviews with responses to each question captured verbatim. These notes were then read back and checked with the participant at the end of the interview and changed as necessary if they identified errors or misunderstandings of what they intended to say.

The characteristics of nurses and patients who agreed to be interviewed are presented in Tables 10.2 and 10.3. Only two of the interviewed nurses completed the knowledge and PHASe attitude questions at follow-up, so it is only possible to present baseline means of these subscales in the nurse table. All interviewed nurses reported to the interviewer that they had experience of using the HIP with at least one of their study patients. Each one of them had used the HIP at baseline but only one had completed follow-up HIPs with the same study patients at 53 weeks. One of the nurses did not return any copies of the HIP form to the study team but in the interview stated they had completed a baseline HIP with one of their study patients and had attempted, but not completed it, with another. The subsample of interviewed nurses were slightly more likely to work in a forensic team, have a degree or a general nursing qualification than the baseline trial nurse sample. There were slight differences in the adapted PHASe subscales mean scores. Knowledge scores were 1.7 points higher and attitude and confidence scores 1.7 points lower in the interview sample but there were no other discernable differences between them.

Medical comorbidities reported by the patient sample included allergy (hay fever) and chronic musculoskeletal problems (due to injury). There were two thirds less medical comorbidities in the interview sample than that seen in the total trial sample. Family history of cardiovascular disease was present in a quarter of the total trial sample but had not been reported in the interview sample. Only one patient in the interview sample was prescribed medication for CVD (a statin and an antihypertensive). Half of the interviewed patients were prescribed clozapine.

## Table 10:2: Baseline characteristics of nurses who were interviewed

| **Group**<br>**Number of CMHNs** | | **Part 2 nurses at baseline**<br>n=5 unless stated<br>X (%) or mean (sd) | **Part 1 nurses at baseline**[a]<br>n=51 unless stated<br>X (%) or mean (sd) |
|---|---|---|---|
| **NHS Site** | 1 | 2 (40%) | 24 (47.1%) |
| | 4 | 3 (60%) | 13 (25.5%) |
| **CMHT Type** | | | |
| | Recovery | 4 (80%) | 31 (60.8%) |
| | Forensic | 1 (20%) | 3 (5.9%) |
| **Age** in years at consent | | 52.4 (5.2) | 45.6 (7.8) |
| **Gender** | Female | 3 (60%) | 36 (70.6%) |
| **Ethnicity** | White British | 4 (80%) | 45 (88.2%) |
| **Grade** | Band 5 | 5 (100%) | 1 (2%) |
| **Highest Academic level** | Certificate | 1 (20%) | 11 (21.6%) |
| | Diploma | 2 (40%) | 14 (43.1%) |
| | Degree | 2 (40%) | 22 (27.5%) |
| **MHN Experience** in years | | 13.6 (9.9) | 14.9 (8.1) |
| **Time in post** | 1 – less than 5 years | 2 (40%) | 22 (43.1%) |
| | 5 – less than 10yrs | 3 (60%) | 18 (53.3%) |
| **Adult nursing qualification** | | 1 (20%) | 4 (7.8%) |
| **Knowledge** MCQ (baseline) | | 11 (3.5) n=4 | 9.3 (2.4) n=51 |
| **Attitude** PHASe (baseline) | | 28.8 (4.4) n=4 | 30.4 (5.2) n=38 |
| **Confidence** PHASe (baseline) | | 12.5 (4.6) n=4 | 14.1 (3.8) n=38 |
| **Barriers** PHASe (baseline) | | 30.5 (2.6) n=4 | 30.6 (3.2) n=38 |
| **Attitude towards smoking** PHASe (baseline) | | 19.5 (4.8) n=4 | 19.7 (3.5) n=38 |

a = nurses that returned adapted PHASe at baseline

**Table 10:3: Baseline characteristics of patients who were interviewed**

| Group | | Part 2 patients at baseline | Part 1 patients at baseline |
|---|---|---|---|
| **Number of patients** | | **n=6** | **n=173** unless stated |
| | | X (%) or mean (sd) unless stated | X (%) or mean (sd) unless stated |
| **NHS site** | 1 | 3 (50%) | 95 (54.9%) |
| | 3 | 3 (50%) | 48 (27.7%) |
| **CMHT type** | Recovery | 4 (66.7%) | 119 (67.1%) n=166 |
| **Months on caseload** | median (min,max) | 24 (9,84) | 29 (1,300) n=161 |
| **Primary Diagnosis** | Schizophrenia | 6 (100%) | 110 (63.6%) n=172 |
| **Age** in years at consent | | 42.7 (11.6) | 46.3 (12.1) n=170 |
| **Gender** | Male | 4 (66.7%) | 96 (55.5%) n= 170 |
| **Ethnicity** | White British | 5 (83.3%) | 156 (90.2%) n=171 |
| **Living status** | Lives alone | 4 (66.7%) | 97 (56.1%) n=171 |
| **Relationship** | Single, divorced or widowed | 5 (83.3%) | 117 (67.6%) n=169 |
| **Smokes cigarettes** | | 3 (50%) | 107 (61.8%) n=167 |
| **Medical Comorbidity Diagnosis**[a] | None | 4 (66.7%) | 42 (24.3%) n = 169 |
| | 1-4 comorbidities | 2 (33.3%) | 115 (66.5%) n = 169 |
| **Total number of medications** | median (min,max) | 2.5 (1,5) | 4 (0,20) |
| **Total number of antipsychotics**[a] | | | |
| | One | 5 (83.3%) | 151 (92.1%) n =164 |
| | 2 or more | 1 (16.7%) | 26 (15%) n =164 |
| **Prescribed an atypical antipsychotic** | | 5 (83.3%) | 112 (64.7%) n=164 |
| **Prescribed a typical antipsychotic** | | 2 (33.3%) | 51 (29.5%) n=164 |
| **Family History of cardiovascular disease (CVD)** | | 0 (0%) | 44 (25.4%) n= 156 |
| **Prescribed medicines for CVD**[a] | | 1 (16.7%) | 46 (28%) n=164 |

a = includes medications for diabetes, dyslipidaemia and hypertension

## Part 2 patient interview results

Six patient interviews were conducted either at the patient's home (n=5) or community team base (n=1). Interviews lasted around 30 minutes. Fifty percent (n=3) patients interviewed recalled the HIP process although of these two had no record of a HIP being returned in Part 1. When patients did not recall the HIP at all a copy was shown to them in the interview (n=3). One of these patients commented on why it had not been completed as planned saying

> "it's a shame, with all the cutbacks that change of nurse and team meant that the HIP was not done" [Participant 5].

Thematic analysis of the written record of responses to the 9 questions using NVivo Version 10 and the constant comparative method described in the methodology chapter identified five themes related to the use of the HIP: the HIP as an unobtrusive tool, enhancing the nurse-patient relationship, the importance of regular health checks, quicker pathways to care and changing health behaviour.

**The HIP as an unobtrusive tool**

Two participants talked about the HIP as something that didn't take over their sessions with their nurse, but added to them.

> "Aware of it 'in the background' most of the time but more aware during the assessments, obviously… [the HIP] gave a reminder of the importance of physical health which continued throughout the other sessions, not always addressed, but 'always in mind'" [Participant 2]

> "Not really that aware – remember doing it, but not really at other times". [Participant 3]

One participant who had experienced the HIP process talked about feeling as if the focus on physical health helped them feel like they were treated as a person, not just being viewed in the context of their diagnosis.

> "Just more rounded, more complete. Felt more valued and less like it was 'all about my diagnosis or index offence" [Participant 2].

**Enhancing the nurse-patient relationship**

Two participants thought the use of the HIP meant they felt more engaged in the relationship with their nurse.

> "I felt like I was being valued, taken seriously. It helped build trust and the therapeutic relationship" [Participant 2].

> "What I will say is that the HIP helped my nurse and I communicate about my needs more, and I felt listened to… I have had various health problems and it was nice to be able to talk about them and feel listened to" [Participant 3].

A third participant who recalled having a HIP done commented that they preferred having physical health care from their CPN because

> "it is good to be followed up by someone you know unlike the GP and nurse at the practice who are all different people" [Participant 6].

**The importance of regular health checks**

All six patients who were interviewed said they thought it was very important to have regular health checks.

> "If I have diabetes, I would like to know straight away so I can go on medication. If I get diabetic checks done monthly that will give me a peace of mind… regular weight checks help me to keep an eye on my weight. I would also like regular drug screenings as well. That will keep me out of trouble. Heart checks and blood pressure will be very helpful if possible." [Participant 1].

> "Very important, at least every year, maybe more often. It's important for nurse to remember that the patient is a whole person and important for the patient to focus on what they have to do for themselves to be healthy". [Participant 2].

> "I have no real opinion as to whether it should happen at a certain time or not, but I do believe it should be used, especially if like me there are physical health problems that have not been previously addressed". [Participant 3].

> "Yes, rather with my CPN than my GP" [Participant 4].

> "Yes, I think it is important every year" [Participant 5].

> "Definitely at least one a year, it's eye opening for the person" [Participant 6].

**Quicker pathways to care**

Two participants talked about experiencing a quicker process in addressing their physical health needs due to use of the HIP.

> "It did seem to get my problems looked at quicker though, particularly referrals to the GP" [Participant 2].

> "Quicker speed of referral, better communications, especially with my GP and my CPN… more happy with the overall standard of care" [Participant 3].

**Changing health behaviour**

Three participants talked of positive life changes as a result of an increased focus placed on their physical health since use of the HIP. Two described making specific health behaviour changes (starting swimming or walking, reducing the amount they smoked, decreasing their caffeine, drug and alcohol use) and one also described how they believed these changes had helped them get and keep a voluntary job for the last 6 months.

> "Yes – cigarette use has fallen, decreased levels of alcohol and drug use. Some of these changes happened prior to HIP, but using it has helped keep focus on why these changes were made an helped maintain the healthy behaviours" [Participant 2].

> "It made me look at caffeine. I was drinking 10 bottles of coke. Have stopped that all together, and am drinking squash now… I have taken up walking to help with my weight" [Participant 6].

> "On a wider level these [health improvements] have enabled me to get a volunteering job, the first job I've had, and keep it for 6 months now". [Participant 2].

The other three patient participants commented on how they had not implemented health behaviour change that had been suggested to them (e.g. starting swimming, going to the gym, introducing a healthier diet) stating they were not motivated to change (one commented they were "far too old" to make any changes to their lifestyle).

## Part 2 nurse interview results

All interviews were conducted at the nurse's team base with the exception of one telephone interview and lasted around 40 minutes. All interviewed nurses stated they had experience of using the HIP with at least one of their study patients. Each one of them had used the HIP at baseline but only one had completed follow-up HIPs with the same study patients at 53 weeks. One of the interviewed nurses had not returned any copies of the HIP to the study team but in the interview stated they had completed a baseline HIP with one of their study patients and attempted, but not completed it, with another.

Analysis of the transcripts using NVivo version 10 and the constant comparative method described earlier initially generated twelve coded themes that were collapsed and summarised into seven final themes; the importance of physical health to holistic (nursing) care, uncovering physical health needs, health literacy (nurses), health literacy (patients), assessment is easier than intervention, communication of evidence and organisation of services.

### The importance of physical health to holistic (nursing) care

In this theme, all five nurses identified the HIP as something that helped them maintain a focus on physical health care within their role. They talked about physical health care as an important part of providing holistic care, that physical health care was seen as located

within their role by the other workers in their team and was important to the care of their patients.

> “Other members of the team could see the benefits [of the HIP Programme] however it was seen as a nurse initiative and role… [it was] good for my practice as it raises awareness of physical health” [Nurse 1].

> “You do have this label of nurse which does even just subconsciously say or suggest you should know something about these things you know. If we are talking holistically as well, physical is part of that holistic care” [Nurse 2].

> “I think this in some ways gets us back to our basic skills of actually a holistic approach to care” [Nurse 3].

> “Somebody comes onto the caseload… what might be considered a more mundane thing such as peoples kind of dental history their uh their eyesight um generally sexual health issues so there’re a lot of things that um that um won’t be won’t be available to you in terms of their sort of um written information that’s passed onto you so really its then very much down to you as a as a community mental health nurse to um to ask to ask those questions” [Nurse 4].

> “[It’s] quite a major issue with a lot of our um community patients they tend to be on the more severe of the spectrum as far as their mental health is concerned or their mental health has been in the past consequently they’re also on lots of medication generally they also tend to have had substance misuse problems in the past as well um and all these things kind of sort of complicate the picture as far as their physical health is concerned so I think to actually have some form of structured assessment it’s very useful in fact I’d almost say it’s kind of vital looking to the future” [Nurse 4].

> “It has had an impact there’s been a total and utter reminder um of everything that we don’t do and um it’s made me now every time I have a new patient or I’ve got someone I am vigilant, basically I’m become sort of vigilant with the physical side of stuff” [Nurse 5].

> “I think we can use that in a different way in a more positive way with them to say well let’s look at your diet you know what about [X] prescription you know giving them some solutions, some you know solution focused answers to these problems rather than just saying to someone randomly when you see them every six months you know you still haven’t lost any weight” [Nurse 3].

> “I just incorporate it now you see and go for whatever is needed then and nothings left to chance” [Nurse 4].

**Uncovering physical health needs**

In this theme, the nurses talked about how completing the HIP bought previously unknown information about the patient's physical health into awareness. Alternatively where physical health needs were already known, the HIP acted as a reminder of the importance of keeping these physical health needs on the agenda. One nurse commented there was no other structured way of knowing about all the physical health parameters when a patient joined their caseload.

> "Picking up things that the patient would definitely not gone to their GP for - not without some of our team being involved in that negotiating that with the GP yes that wouldn't have happened without the HIP" [Nurse 3].

> "You can kind of see at a glance the things that that you need to kind of address with them with the patient themselves as far as the physical health is concerned sometimes those are quite surprising you know. Well they were for me, things that I didn't know and I wasn't aware until I wasn't aware of until I'd done the questionnaire um with people and there are things that maybe you know patients have never kind of thought about in relation to their physical health" [Nurse 4].

> "[What] the HIP did was either to highlight a physical health issue that I wasn't aware of and I sort of then kind of build that into the physical healthcare plan or physical health care provision for that for that patient so it would either highlight you know a problem that you weren't aware of or it would kind of act as a sort of reminder for something that you were aware of" [Nurse 5].

> "[X] went to the GP's about her eyes and she actually had to have an appointment at the [Hospital] so that was very good, the questionnaire prompted something that we would have missed" [Nurse 5].

> "Her liver function test was way out of date and in actual fact that was because we'd had changes in consultants an awful lot and it hadn't been followed up and it did pull that up… there was another one that it highlighted that wasn't done um I think it was the lipids… I don't think we ever do tests for cholesterol so it changed what we did in that respect" [Nurse 2].

**Health literacy (nurses)**

In this theme, the nurses spoke about how using the HIP had made them reflect on their lack of knowledge, confidence or competence around physical health and do (or consider doing) something about it.

> “Clinical skills needed jenning up on, an awful lot of these things… the blood pressure one I did because I was having to use it… look it up or ask colleagues (I did both) and practice on each other… it was surprising how much of us didn’t know… so that in itself having to complete that questionnaire made you think I need to look these things up” [Nurse 2].

> “My knowledge…. with menstrual cycle as well believe it or not it’s more personal what I know as a woman than what I know as a nurse… but it prompted learning I did go and look up some menstrual cycle stuff [on the internet] and I did actually go and talk to a midwife [about hormones] and asked colleagues as well” [Nurse 2].

> “I maybe need to do a bit work on myself is around fluid intake, caffeine intake um urinary flow and those kind of inter related issues which have been highlighted in one or two of the questionnaires that I’ve carried out with patients. I think it’s probably down to me to do a bit more kind of research in those areas myself” [Nurse 4].

> It’s years since I have been in education. Like more than and less than and little mathematical things like that I just had to sort of think about because I’ve just been out of education for so long I never did maths anyway um so you know it’s just again looking at a different document isn’t it and just getting your head round it” [Nurse 5].

> “it’s about getting nurses to pick up the pieces and to become experts in their field really within the mental health field but where it overlaps with physical healthcare, not be afraid to go and spend some time at the sleep clinic and see what they, how they diagnose and what are [the best interventions]” [Nurse 5].

**Health literacy (patients)**

In this theme, the nurses discussed the benefits of having a physical health conversation and using feedback from the HIP to raise awareness of the patient’s need for health behaviour change.

> “It’s giving evidence to the patient… they’re finding that themselves it’s not us having to say well they’re saying “oh actually” when you say that that’s that and it gives them that boost that motivation to actually look at ways they can address it and the support groups that are available out in the community for them to do that… it gives them a time line as well because if you’re going back like we went back they wanted to be focused to try and do something about it so that when we complete the next um profile they’ve actually they have achieved they have and they’ve looked at their own wellbeing and what they can do to address some of

those needs it's making them a bit more self-aware as well and more in control of their wellbeing" [Nurse 1].

"I didn't realise you know is the sort of attitude of the other person when they listen, and so they got talking about what their physical concerns were so even it raised their awareness to a new level completely, not just to talk to a nurse or a health professional but actually with their own [partner]" [Nurse 3].

"They're finding that [out] themselves it's not us having to say well they're saying oh actually when you say that's that and it gives them that boost that motivation to actually look at ways they can address it and the support groups that are available out in the community for them to do that" [Nurse 1].

**Assessment is easier than intervention**

Nurses talked about how it was relatively easy to undertake physical health assessment using the HIP and that patients welcomed the focus on physical health measurement from them. One nurse thought it may be an advantage to build trust to initially focus on physical health, rather than the usual focus on mental health and risk early in the nurse-patient relationship. Two nurses talked about paying more attention to parameters they felt more comfortable talking about. Barriers were experienced when trying to implement a health care plan. Some of these barriers were related to the nurse's own practice, some to resistance from patients and some to systems (organisational) factors.

"I think doing the questionnaire can actually be a way of helping build your relationship with that person when they first come on to your caseload. You're not having to ask the kind of more intrusive questions about their mental health that they may find more difficult in trying to answer. Indirectly I think it might help in sort of building that relationship" [Nurse 4].

"[it is] easier to do blood tests and physical monitoring, take your temperature and can I take your blood pressure, those sorts of very practical things were very easy. I think that the service user's actually like that sort of medical attention" [Nurse 1].

"[I] would make a clinical judgement about asking certain questions or not, for example if I anticipated it would make the patient verbally aggressive towards me… particularly with the diet and the caffeine and the all those sorts of things and the sleep um but the things like the waist circumference… things that they perceive to me as becoming a nag about. People might even become a bit more resistant through you asking them (talked about the sighing sound heard from the patient when asking questions about diet)." [Nurse 2].

"Actually implementing the care plan is often the most difficult… um physical health tends not to be a priority a lot of the time for us as practitioners so it is more about the implementation of a care plan and um you know I'll hold my hand up and say I could have been better implementing parts of physical healthcare plans" [Nurse 5].

"I don't, didn't like the um you know the bit about the sexual side of stuff I think that's very difficult for us to ask" [Nurse 5].

"I don't think um the patients found it all that difficult I mean, the safer sex and the sexual satisfaction, some of those questions you're probably more embarrassed than the patients were in asking them you know um I mean even if the answer was they weren't… yes I think that's interesting that's something once you ask the question you get quite a reasonable response)" Nurse 3].

"With the kind of patient group that we're dealing with getting them actually to go to an optician can take take you ages" [Nurse 1].

"That's more of a sort of technical issue really about getting the GP's to do the blood samples and also getting the patient down to the GP to have a have a sample have the samples taken" [Nurse 4].

"I tell you what it did lead on to, an awful lot um um opticians and dental referrals. I would think that they increase more because I think you're comfier asking about that sort of thing" [Nurse 2].

"Talking about medication and obesity with patients is probably more of a sensitive issue than sex. I wasn't embarrassed about asking about their weight and you know what are you going to do about it, and that was the one that probably there was slightly more confrontation over" [Nurse 2].

**Communicating evidence**

In this theme the nurses talked about how the HIP allowed evidence of physical health need to be more easily communicated to patients and GPs.

"We have the evidence there to support physical health needs which I found quite useful and I think that helped the service user um address the needs that they needed to and be listened to, aided communication with consultant reviews and provided specific evidence to GP of need. It's like it almost builds that relationship working relationship with GP's" [Nurse 1].

"It's giving evidence to the patient… they're finding that themselves it's not us having to say" [Nurse 1].

> "I feel by having this addressed in their wellbeing plan they always get a copy of the wellbeing plan so that sort of looks at physical health needs they're aware and that makes also future appointments for the service user a lot more it's more beneficial" [Nurse 1].

> "it gives [patients] a time line as well because if you're going back like we went back they wanted to be focused to try and do something about it so that when we complete the next um profile they've actually they have achieved they have and they've looked at their own wellbeing and what they can do to address some of those needs it's making them a bit more self-aware as well and more in control of their wellbeing" [Nurse 1].

**Organisation of services**

In this theme systems that supported and prevented successful use of the HIP process were highlighted, this included access to equipment and regular training updates but also issues related to workload and caseload pressures, and recent reconfiguration of services that were perceived as preventing follow-up and the implementation of physical health interventions. Problems with interface communication and working with GPs were also highlighted in this theme.

> "[There was] lots of scrabbling around looking for it, tape measures and things like that" [Nurse 3].

In contrast another nurse highlighted how having the right equipment was now on the team's agenda.

> "[In the team's six weekly business meeting] part of the time is set aside to talk about how we're monitoring physical health and whether or not we need more equipment… they've bought a portable weighing scales and portable height measuring thing so these are things that you know we weren't getting the money for before" [Nurse 3].

Two nurses commented on how the recent introduction of mandatory physical health training updates by the Trust was positive and highlighted management support for the role.

> "The physical health training recently introduced by the Trust is positive to make sure everyone up to speed and at the right level in their practice" [Nurse 1].

> "We're now being sent on training and various other things so there's some things in the trust though there are some negatives in the way that our caseloads have been managed over the last year I think on the health side of it, I think there is a

recognition that this is really important… skill sides they're actually making sure that we're up to date and you know that's something that wasn't on the agenda before" [Nurse 3].

Time and workload pressures were discussed in relation to the need to see patients often and for long enough time to conduct an annual health check and implement interventions, despite an acknowledgement of the importance of doing so. Nurses discussed the difficulties of balancing workload pressures with including the HIP process in their work. They emphasised the work required after completing the HIP as the most time-consuming.

"From my experience it, to actually effect a behaviour change generally it will require revisiting the issue quite a number of times before you'll see uh a definite change" [Nurse 4].

"Having enough time to complete the HIP (including looking back at past results and the trail afterwards) with everything else there is to do. Some items took more time as needed explanation (bowels, sexual parameters) – service users were sometimes surprised by the questions so needed time to explain. It increased my workload to do it properly" [Nurse 1].

"[It] created more follow up stuff because if I'd asked and got a negative response that needed chasing up it had a sort of knock on effect because once you've identified that you can't just leave it" [Nurse 2].

"it's a high value in that on that half an hour spending to get to know to get to know a lot more about the physical health of somebody that you're caring for in the community um so that's a half an hour well spent I think… where it can get time consuming um is if there are issues that are highlighted and then you're then following those up that that's where it can get time consuming and that's not a fault of the questionnaire. I mean in a way that's a plus of the questionnaire because um if you don't do something about that those issues or somebody doesn't do something about those issues then probably you know that's got serious consequences for the patient further down the line" [Nurse 4].

"it's not just about completing the form… it could stop you doing other things that are important such as… the relapse prevention all the things on the care plan the wellbeing plans all those sorts of things that you've got to clock through." [Nurse 2].

"if you're not careful with the pressures of your caseload um things like patients physical health can be put to one side because they're not pressing they're not pressing issues very often" [Nurse 4].

The perceived impact of recent changes to services within and outside of their organisation was highlighted as a barrier by nurse participants from both organisations.

> "I think the limitations were more to do with how we're set up to work and what's going on with our Trust than limitations to do to with the project because teams were swapped about a lot and it's still going on so we kept losing patients they would be redistributed so there was no continuity with what you did um you were concentrating on building up the relationships with the patients and probably that first contact where you might have used that [the HIP] but then by the time it had come round to probably doing the follow up bit you had lost the patient [from your caseload]" [Nurse 2].

> I'd only see a very limited role [for the HIP in future practice] because with um as now being pushed to discharge people quicker we wouldn't be able to follow up or know where they're at if they've gone now… and loads of people wouldn't be a year" [Nurse 3].

> "Virtually almost as soon as I'd done, well in fact even before I did the baselines um somebody else took that caseload on" [Nurse 5].

There was the observation from one nurse that (since reconfiguration) patients do not get a care coordinator (at Agenda for Change Band 6) unless they relapse but remain on a large maintenance caseload of a Band 5 nurse who has tasks to complete that prevent them from implementing health behaviour interventions.

> "They don't get a Care-Coordinator unless they relapse and I think that is a big issue that we are struggling with. As we are now seeing band 5 nurses do not stay very long [they] tend to be people who have just qualified and as soon as they get a chance of a six somewhere else they're going to move on so they're really quite elusive fluid group of people… by their very nature they're only going to be six months to a year [in post] and they're going to move on… They are doing very set tasks like depots, like medication management issues and then there is an impact on whether they have the time to look at wider health" [Nurse 4].

One nurse talked about the disappearance of useful local NHS resources.

> "What resources we've got available as well it that um really sort of kicked off with diet, exercise, smoking. We had a new NHS resource set up in the town so it made it very easy for us. We identified this, asked people if they were interested, they'd get one to one support but then the funding was pulled and we lost that and I think there was a few things like that so you just get a bit sort of downhearted" [Nurse 2].

There was an expressed willingness to work with primary care but frustration that communication and co-working is difficult to achieve because it is not usual practice and systems are not set up to facilitate this easily.

> "The issues with it are how we follow it up and how we how we um sort of interconnect with other health services to actually follow up the information that comes outs of the questionnaire, It's not the questionnaire as far as I am concerned you could tweak a little bit but the questionnaire the way it's laid out is fine um it's just um how you follow up and follow through the information that you that you get from the questionnaire and the more I think about it the more that really um that sort of entails a better linking between our service and GP services" [Nurse 4].

> "There are some measures in the HIP which although I think are very valid they need to be taken by the practice nurse at their GP surgery and I have asked. I have asked um GP surgeries to do that when I as part of the study uh but again the response from GP's is patchy" [Nurse 5].

> "They [GPs] never come along to the CPA reviews, never known one in all the years" [Nurse 2].

> "[CPA] reviews that GPs do not engage in, sometimes try to do it at the GPs surgery but that's not often possible" [Nurse 1].

> "Obviously all our all our patients will get registered with a GP um but I've found that the interaction between our patients and GP's is very patchy so useful to have a structured checklist very often so again the information is not it's not being um gathered by GP's either so again it comes back to us really" [Nurse 4].

> "[There is the] difficulty of patients coming to the CMHT base in large rural area – would have to go out to surgeries to run a clinic but why aren't GPs and practice nurses doing this? They're about 30,000 some of these GP surgeries with 15 active GP's and I guess the physical health of you know a few thousand people with mental health problems is not their priority" [Nurse 3].

### Part 2: Results of the audit

Lists of patients remaining in Part 1 at follow-up for each of the three audit conditions were identified by one of the Trial Coordinators at Site 1 as per protocol. Field researchers worked though these lists until the sample size was achieved as planned and 30 sets of patient case notes were audited; 10 patients in the HIP group whose nurse had returned at least one HIP to the study team in Part 1, 10 from the HIP group whose nurse had not returned a HIP and 10 patients from the TAU group.

Data was collected by two field researchers based at the NHS site and entered into the HIP Audit form, these were then collated and analysed by myself using SPSS 19. The characteristics of the audit sample are presented in (Appendix 6). There was a greater proportion of patients with a diagnosis of schizoaffective or bipolar disorder in the audit sample compared to the entire Part 1 patient sample at baseline. In the HIP Group where a HIP had not been returned to the study team patients appeared to be more likely to have spent longer on their study nurse's caseload and have a recorded medical comorbidity than patients in the HIP returned group. In the HIP returned group patients appeared more likely to have a record of family history of cardiovascular disease [CVD] and have been prescribed CVD medication. However, the numbers in each group are too small to perform any meaningful inferential statistical tests of significance of these apparent trends. There were no other discernable differences between groups.

During the process of completing the audit questions it was identified that two patients in the HIP not returned group had evidence of completed HIPs in their case notes. Because of this the results of the audit analysis are presented in per protocol groups, i.e. in groups where there was any evidence of HIP completion (Table 10.4).

**Table 10:4: Audit Table (per protocol version where HIP completed even if not returned)**

| Group | | HIP completed | HIP not completed | TAU |
|---|---|---|---|---|
| **Number of patients** | | **n=12** unless stated | **n=8** unless stated | **n=11** unless stated |
| | | X | X | X |
| **Any record of physical health check** | | 8 (66.7%) | 3 (37.5%) | 3 (27.3%) |
| **HIP recorded** | | 7 (58.3%) | 0 (0%) | 0 (0%) |
| **Who completed heath check** | Consultant | 0 (0%) n=8 | 0 (0%) n=3 | 1 (9.1%) n=3 |
| | Junior doctor | 2 16.7%) n=8 | 1 (12.5%) n=3 | 1 (9.1%) n=3 |
| | Nurse | 6 (50%) n=8 | 2 (25%) n=3 | 0 (0%) n=3 |
| | Other | 0 (0%) n=8 | 0 (0%) n=3 | 1 (9.1%) n=3 |
| **Care planning** | | | | |
| Care plan was available to audit | | 7 (58.3%) | 5 (62.5%) | 6 (54.5%) |
| Use of HIP identified | | 3 (25%) n=7 | 0 (0%) n=5 | 0 (0%) n=6 |
| Needs | | 6 (50%) n=7 | 4 (50%) n=5 | 4 (36.4%) n=6 |
| Interventions | | 5 (41.7%) n=7 | 3 (37.5%) n=5 | 4 (36.4%) n=6 |
| Outcomes | | 3 (25%) n=7 | 2 (25%) n=5 | 2 (18.2%) n=6 |
| **Care Programme Approach [CPA]** | | | | |
| CPA document was available to audit | | 7 (58.3%) | 5 (62.5%) | 8 (72.7%) |
| Use of HIP identified | | 0 (0%) n=7 | 0 (0%) n=5 | 0 (0%) n=8 |
| Needs | | 5 (41.7%) n=7 | 5 (62%) n=5 | 5 (45.5%) n=8 |
| Interventions | | 5 (41.7%) n=7 | 5 (62%) n=5 | 5 (45.5%) n=8 |
| Outcomes | | 5 (41.7%) n=7 | 5 (62%) n=5 | 2 (18.2%) n=8 |
| **Record of communication with primary care** | | | | |
| Use of HIP identified | | 0 (0%) | 0 (0%) | 0 (0%) |
| Needs | | 9 (75%) | 3 (37.5%) | 8 (72.7%) |
| Interventions | | 9 (75%) | 3 (37.5%) | 10 (90.9%) |
| Outcomes | | 9 (75%) | 3 (37.5%) | 8 (72.7%) |

Other than where a HIP had been entered into the record and completed by a nurse (n=9) all other reported health checks were by medical staff (n=5) and one 'other" (a health care assistant). There was no evidence of any increased interface communication with primary care or in CPA documentation in the HIP group patients. In all three groups this evidence existed in the record for patients who had health checks recorded or not.

## Chapter summary

In this chapter the results of the nurse outcomes in the trial and the outcomes of the process observation were reported. Due to poor follow up rates of the adapted PHASe it

was not possible to assess the impact of the HIP Programme on CMHNs attitude towards or knowledge of physical health care (Objective 4). There were few discernable differences between CMHNs in the HIP Group who returned a copy of the HIP to the study team and those who didn't other than male gender and working in an assertive outreach team at baseline (more likely in the HIP not returned subset). No harms were reported related to participation in the research.

A third of all invited HIP group nurses agreed to the Part 2 interviews but only fourteen percent of invited patients. The interview samples were broadly representative of the baseline trial sample, although the nurse sample were more likely to be educated to degree level and have ever used a HIP and the patient sample were more likely to be prescribed CVD medication. All the interviewed nurses reported they had used the HIP at least once and half of the patients recalled having a HIP completed. This was new information to the research team, because copies of the HIP had not been received for one of the nurses and patients. That return by post was not a reliable method of capturing HIP completion was supported by the HIP Audit results where 2/10 patients in the HIP not returned group had a record of HIP completion in their patient record. In the audit patients in the HIP group with evidence of HIP completion were a third more likely to have had a health check undertaken by a nurse than in the other groups. There was no evidence of any impact on the care planning processes or communication with primary care.

Interviewed patients reported the HIP process as unobtrusive and that they believed it enhanced the relationship they had with their nurse, enabled a regular health check and facilitated quicker access to care. There was some ambivalence expressed about the potential of the HIP to change health behaviour, with half reporting they had made positive changes and half stating they experienced internal motivational barriers to change. Nurses highlighted how the HIP Process raised the profile of physical health in their work and enabled them to uncover previously unknown physical health needs in patients prompting them to reflect on and attempt to enhance their knowledge and skills. Physical health conversations and specific HIP feedback to patients was identified as positive. However barriers were experienced when attempting to move beyond assessment to intervention. These comprised internal (resistance to change,) and external (organisational) factors.

# Chapter Eleven: Discussion of the outcomes of the trial and process observation

## Patient outcomes in the Cluster RCT (Part 1)

The fieldwork for this trial was undertaken in generic and specialist community mental health services across the East of England between May 2011 and April 2012. Baseline scores for the SF36v2 PCS and MCS indicate our sample was similar to community patients with SMI in the USA, and primary care patients with at least one comorbid long-term physical health condition in Germany (Wang et al., 2008, Druss et al., 2001). Where the HIP was completed at baseline a mean of 6.6/27 (SD 3.5) items were marked red per patient, this is consistent with the level of comorbidity identified in our community case series in Lanarkshire in Scotland (Shuel et al., 2010). An RCT of joint crisis plans reported similar baseline demographics to our sample in a study of 569 SMI patients from generic and specialist community mental health teams (Thornicroft et al.). These authors reported a more ethnically diverse sample than ours, but patients were recruited from sites serving the three largest urban areas of England, as opposed to our mixed urban (but largely) rural county population. The characteristics of our patient sample therefore indicated that the Part 1 trial results can be generalised at least to SMI patients of secondary community mental health services in England outside of major cities.

Randomisation was effective, as demonstrated by the lack of discernible differences between patient demographics across the two groups. We had robust procedures for maintaining researcher blinding and there were no breaches during the trial. In a population where attrition rates in clinical trials can be considerable we achieved a 74% follow up at 12-months despite tightly defined timings for patient assessment. A threshold of 80% is often used to separate “high”- and “low”-quality” randomised trials, and by some journals as a threshold for publication (Sackett et al., 2000, Brueton et al., 2014). The 26% attrition we experienced may have introduced bias and reduced power because, for example, patients who remained in the trial at follow up were more or less motivated towards making physical health related lifestyle changes.

The intention to treat analysis demonstrated there was no effect of the intervention on the primary or secondary outcomes. Intent-to-treat principles are applied in randomised controlled trials to avoid biases associated with non-random loss of participants. Analysis of the primary outcome was based on sample sizes of 68 and 60. On the surface this seems underpowered compared with the 32 nurses with three consented patients each planned for. However, our sample size calculations assumed a within cluster correlation of 0.1 or 0.2 for 80% and 86% power respectively. The intra class correlation obtained in the

study was substantially lower (0.036) than that planned for and average cluster sizes in the two randomised groups were 2.7 and 2.5 respectively. Rough retrospective power calculations, although not usually recommended, for cluster sizes of 2 or 3 with an ICC of say, 0.05, suggest power of over 80% to detect an effect size of 0.55 standard deviations. Hence our study may not be underpowered. The 95% confidence interval for the SF36v2 Physical Component Score [PCS] suggests that the intervention may reduce PCS by 1.5 points or increase it to 4.5 points compared to TAU but I have been unable to identify any published evidence that this is clinically meaningful in SMI.

Patient baseline scores on the primary outcome measure (SF36v2-PCS) indicated considerable physical impairment in both groups. There were three patient deaths during the course of the trial, all attributed to cardiovascular disease. Completed HIPs emphasised the substantial physical health problems that patients were experiencing.

That just under half of the patients participating in the HIP arm of trial had a HIP completed and returned to the study team at baseline by their study nurse was unexpected. It is reasonable to assume that few would have implemented interventions subsequent to the baseline assessments. Fidelity to the intervention at 12 months was weak, only 28% of the patients in the HIP Group had a HIP returned by their CMHN at follow-up. If nurses were motivated to sign up to a trial it might be expected that their adherence to delivering the intervention would have been relatively good, but this was not the case. Consequently, that patients' physical health related quality of life did not appear to improve in either the HIP or TAU groups is not surprising as the majority of HIP patients effectively received TAU.

We performed a per protocol analysis of those patients whose nurses who received HIP training and those who did complete and return HIPs, as opposed to those in the HIP group who didn't. The Trial Steering Committee did not define the per protocol analyses a priori and only selected this method after we knew about the poor fidelity to HIP completion. Per protocol analyses (either pre planned or not) are considered acceptable as long as they are labeled secondary comparisons and over inflated claims are not made for efficacy as a result (Schulz and Grimes, 2002). If the per protocol analyses had identified a difference this could only have indicated a trend towards an effect because as well as undermining the equal groups achieved at randomisation, the subsequent analysis was underpowered. However we did not find any evidence of an effect at all in any of the per protocol analyses

Our trial had some notable weaknesses. Less than half of the participating nurses completed HIPs with just under half of the study patients, consequently the study can be justifiably criticised as not providing a straightforward test of the effectiveness of a health check using the HIP in this population. The SF36v2 PCS measures the patient's

perception of their health status. SF36 summary scores may be too broad and general to capture changes in health status over the time frame of the trial and changes to the items used to calculate PCS may take a long time to improve in this population (Simon et al., 1998, Druss et al., 2010). Some authors have criticised the use of generic quality of life scales in SMI due to the impact of psychopathology on accurate judgements of subjective wellbeing (Bobes et al., 2010). A disease specific quality of life measure may have addressed this but a validated measure of physical health related quality of life was not available for all three SMI disorders. More specific measures of health status such as body mass index (BMI) were considered as alternatives but were rejected because collection of health status data from the TAU group would have contaminated the usual care condition.

We had planned in our protocol to calculate CVD risk in HIP group patients using QRISK®2-2013 (a measure of the risk of having a heart attack or stroke over the next ten years) with data from the health check. The low quantity and quality of data from the returned HIPs was such that this was not possible. Clustering in this trial was at the level of the nurse and not the team. We could be criticised for not addressing possible contamination (sharing the HIP Programme knowledge) by nurses working in the same team but in different arms of the trial. We have no evidence this occurred. Randomising at the level of the team may have reduced this risk but would have required more sites to access a sufficient number of teams. Four NHS mental health service provider sites across the East of England were required to achieve recruitment. We were not able to control for the non-specific effects of time spent training nurses and additional time nurses spent with patients completing the health check. We did not monitor and consequently do not know what proportion of patients in the trial had a health check carried out in Primary Care during the study period. Theoretically, a primary care health check might have cancelled out any effect of the HIP but this seems unlikely given the comparatively poor state of participants' health.

Any intervention has the potential to do harm and beyond routine adverse event reporting, we did not monitor any unwanted effects the HIP could have caused. The HIP and training attempted to target physical health screening and intervention in SMI through supporting the existing role of the CMHN. Although pragmatic, this was still a complex intervention that required several interacting components, including engagement and involvement in the process from patients, nurses and multiple provider services. More attention to the feasibility of implementation may have highlighted areas that required attention such as management support, resources, interface communication and working/professional culture.

The trial phase found no evidence that CMHN facilitated health checks following HIP Programme training are effective at improving the physical wellbeing of patients on their caseload. Previous studies have shown that general health checks carried out in asymptomatic people do not reduce morbidity (Krogsbøll L et al., 2012). Despite this, national guidance in England directs clinicians to conduct annual health checks in adults with psychosis and these are now to take place following admission to a secondary care service and then for at least a year (National Collaborating Centre for Mental Health, 2014). A number of small case series have suggested the possible value of health checks in this group of patients in secondary care (Shuel et al., 2010, Bressington et al., 2014, Phelan et al., 2004). This is the first randomised controlled study that provides evidence that challenges the value of health checks provided by CMHNs in this population.

### Nurse outcomes in the Cluster RCT (Part 1)

Outcomes from nurse data collected in Part 1 of the trial were intended to be analysed to test any change in CMHNs attitude towards and knowledge of physical health care at 12 months in the HIP Programme Group (Objective 4). The poor response rate to the adapted PHASe survey at 53 weeks prevented this analysis. Of those nurses in the HIP group who responded at follow-up only seven had enough complete data for analysis.

At baseline, there was considerable contact between field researchers (who were actively recruiting study patients) and nurse participants. Despite reassurances from the NHS sites at the protocol stage that access to the online survey (located on a server at the University of East Anglia) would not be prevented by NHS firewalls, study nurses reported delays and security warnings when trying to access the survey. Those who were confident users of technology ignored these and worked around the problem by cut and pasting the survey web address into a new browser window. Postal questionnaires were issued to nurses who reported problems to field researchers and requested a paper version. The high baseline response rate (85%) reflects that the CMHNs were motivated to consent and participate in data collection at this time point. At follow-up the survey completion window was less synchronised with patient follow-up and contact with field researchers was not routine. Completion at this stage completely relied on nurses accessing and responding to the website link within an email generated from the trial database. A much lower follow-up response rate of 35.7% was achieved despite a two email reminders that included information about how to overcome potential NHS firewall problems. Only 14% (n=7) had complete baseline and follow-up data, not enough to allow a statistical comparison between groups. Response rates to web based surveys amongst health care professionals rarely achieve 20% and can be much lower where there are problems with familiarity and access (Dykema et al., 2013).

Compared to the sample of MHN who responded to the postal questionnaire by the developers of the PHASe (n=585) (Robson and Haddad, 2012), our sample was slightly older, more predominantly female and much less ethnically diverse. The HIP group who returned any HIPs were more similar to Robson's sample in terms of their mean years of MHN experience (13.4 vs 13.3) than the group who did not return a HIP at all (18.6 years experience). These differences may reflect the nature of the South London sample where two thirds of MHN respondents worked in inpatient, rather than community settings. Inpatient MHNs tend to be younger and less experienced than CMHNs because the majority of MHNs start their preceptorship in inpatient services. The age, gender and ethnicity profile of the CMHN workforce in England was last reported in a September 2010 census (Health and Social Care Information Centre, 2011). Our total trial sample was very similar in age and gender to this national sample, but 19% more likely to report White British ethnicity. Differences in ethnicity are not surprising in a sample from mental health provider organisations covering largely rural populations outside of London. In the 2011 general population census, 93% and 92.4% people in the counties of Lincolnshire and Norfolk described themselves as White British (Office for National Statistics, 2013).

When compared visually, the attitude and confidence subscale mean scores of our total trial sample at baseline were lower than in the Robson et al (2012) sample (by 6.1 and 8.2 points respectively) and the perceived barriers subscale mean score was higher (by 6.7 points). The total possible score for each of these subscales is 50 for attitude, 30 for confidence and 35 for perceived barriers so these differences represent a 12% less attitude and 21% less confidence score. The perceived barriers score was 27% higher. It is not possible to analyse whether these differences are statistically significant or a feature of the large disparity between sample sizes (e.g. by paired sample t-tests). Differences could reflect the different context of community work and the community nursing workforce, but it is not possible to compare with the Robson et al data because these authors did not disaggregate community results. There were no discernable differences between randomisation groups in terms of their confidence in performing a physical health role and their attitude towards smoking, similarities that were also seen within the subsets of the HIP Group. There was a more positive subscale score for attitude in the HIP non-returned group compared to the HIP returned group, but the larger standard deviation in the non-returned group indicates this is likely to be a feature of the very small sample size (n=8) rather than a true difference.

The physical health knowledge of nurses was measured with 20 multiple-choice questions [MCQs] that could achieve a maximum score of 20. All nurses who completed the adapted PHASe at baseline completed the MCQs (n=51) with a mean score of 9.3 (sd 2.4). Little is known about the physical health knowledge of MHNs although they consistently identify it as a training need (Robson and Haddad, 2012, Happell et al., 2013). The MCQ result in

the trial was very similar to the baseline results of 46 MHNs who attended a HIP training workshop as part of a regional masterclass series at the University of Huddersfield in 2013. In this cohort mean knowledge was 4.47 (sd 1.5) at baseline with half of the (same set of) MCQs was used (White et al., 2013). The adaption of the PHASe by addition of the MCQs has not been psychometrically tested but the questions were designed (by an experienced nurse educator) to test fundamental knowledge of physical health care for nursing practice (e.g. normal ranges for vital signs such a blood pressure). At the University of Hull, a sample selected from these MCQs has been included in an assessment since 2011 to test the achievement of learning outcomes in undergraduate student nurses at the end of their foundation year. The majority of nurses in Part 1 of the Trial were working in Agenda for Change Band 6 roles that include mentorship of student nurses. It is worrying that experienced MHNs are achieving less than 50% in this assessment. We were not able to test if participation in the HIP Programme led to an increase in knowledge, confidence and attitude that was sustained at 12 months as intended.

The important findings from the nurse data are that randomisation had worked in Part 1 of the trial in terms of equal distribution of nurses between groups and, like other MHNs in the UK, our nurse subjects held predominantly positive attitudes towards physical health care at baseline. Other than membership of an assertive outreach team at baseline, there was no indication from the nurse data of characteristics predicting non-return of a HIP form to the study team. The characteristics of our nurse sample were similar enough to the profile of CMHNs from across England, to indicate that the Part 1 trial results can be generalised at least to CMHNs working with patients with SMI outside of London.

### Part 2 Process Observation

The process of using the HIP, including patient and staff experience and impact on communication and care planning was explored (Objective 6). The response rates for nurse and patient interviews were disappointing but reflect the difficulties of keeping participants in the study beyond the trial phase and the lack of resources available to do so.

Part 1 of the trial did not include medical staff although they were informed of participation of their patients by letter (a year or more before the interview invitation). Within the resources available in the grant it was only possible to contact psychiatrists and GPs by post in Part 2 and this method of recruitment completely failed. The Trial Steering Committee promoted recruitment in the NHS secondary care sites, including updates and information about the progress of the trial to all staff via the Trust bulletins. There was no promotion of the study in primary care although a personalised invitation letter and stamped addressed return envelope for response slips were used. GP response rates

may be improved by a personalised approach, monetary incentives and promotion by professional associations (Cho et al., 2013). We cannot be certain if the failure of response was due to a failure to receive or open the invitation letters, a lack of interest or time to complete the response slip or prioritise a telephone interview, or a general lack of awareness of the HIP Programme.

The method of recruiting nurses and patients meant that it was not possible to be certain if those recruited had experienced use of the HIP clinically before their interview. Part 1 of the trial tested the results of the HIP Programme so it seemed reasonable to target patients who had been successfully followed-up and their nurses to maximise the ability to recruit participants who had some experience of this process. The only measure of completion of the HIP available to the research team was that a copy had been returned. The interviews demonstrated that this was not a reliable measure. Study nurses and patients who had not returned HIPs described using them in practice and the audit demonstrated documented evidence of use that did not match the record of returns. Despite this, a third of patients and a fifth of nurses interviewed stated they had not been able to implement a HIP. These are participants who were motivated enough to participate and stay in the study beyond the 12 months trial phase, supporting the evidence from Part 1 that there were significant barriers to implementation.

The audit indicated that where a HIP had been used there was evidence of a physical health check in the secondary care patient record. In the groups where there was no evidence of completion of a HIP, there had been less health checks and they were more likely to have been completed by a doctor than a nurse. In the first published case series of the HIP improved interface communication was reported through sharing of the HIP form with GPs, but this was due to the efforts of one senior nurse (Shuel et al., 2010). In the trial there was no evidence of improved interface communication. Evidence within the Care Programme Approach documentation appeared to point to a standardised method of recording physical health need and communication with GPs, rather than an individualised approach that could be corroborated elsewhere in the patient record.

The overarching theme (or meta theme) from the analysis of the interview data was that the HIP was experienced as a useful tool to promote health and wellbeing. However, its routine application was inhibited by barriers in the areas of clinical engagement and organisation of CMHNs' work. There was some discrepancy in the nurses' expressed views about practising outside of traditional CMHN boundaries, compared with those of the patients. Patients valued the HIP experience and welcomed MHN taking a stronger interest in their physical health care. Nurses stated they were motivated to develop their health literacy and role, but struggled to communicate across service interfaces and involve patients in interventions after assessment. Where the HIP indicated a referral was

required, those to dentists and opticians were reported as easier to facilitate than those to primary care. Despite the increased emphasis placed on the need to talk about sex when using the HIP in the training part of the intervention, two of the interviewed nurses were inhibited to do so. All patients had been motivated to try to implement lifestyle changes but all nurses except one (who worked in a forensic team) reported being unable to evaluate their progress due caseload pressures and a reported shift of focus to crisis care through reconfiguration of services. It is interesting that half of the interviewed patients were prescribed clozapine. Clozapine patients remain on a CMHNs caseload over time when relatively well because prescribing and monitoring is not usually accepted by GPs (due to specific monitoring and dispensing requirements).

There is evidence that service reconfiguration has had a negative impact on the quality patient care and staff morale at the highest recruiting study site (Care Quality Commission, 2015, NHS England, 2014). It is also reported that where providers have disbanded their assertive outreach services and redistributed patients and caseloads there has been an increase in the patient suicide rate (National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2013). It is difficult to see how the new policy of annual health checks provided in secondary care can be achieved with a secondary care workforce who remain ambivalent about such a role and have limited time to spend with SMI patients who have recovered from an acute episode of illness.

There were a number of important limitations that should be considered when interpreting the results of the process observation. The study took place in two mental healthcare organisations in the UK that have made a considerable investment in establishing and supporting the HIP. The experience of the HIP in other organisations may be different. The research group, who collectively hold largely positive views about the HIP, may have introduced bias in the phrasing of questions and how the analysis was performed. There was tension in the analysis stage between attempting to minimise observer bias and needing to understand the context of the data. An example of this is where NVivo identified a subtheme when the only evidence was a quote from one participant who had not used the HIP. Due to this and a wish to understand which nurses and patients had actually experienced the HIP, there was a return to hand coding data and themes. Finally, only small numbers of MHN and patients were available to participate and we were unable to reach a point where we were confident that we had achieved saturation of data.

## Chapter summary

The trial phase was well conducted, randomisation was successful and blinding of data collectors was maintained. The intention to treat analysis demonstrated no effect of the HIP Programme on the primary outcome or any of the secondary trial outcomes and this was supported by per protocol analyses that explored outcomes where there had been

fidelity or not to the intervention. Fidelity to the intervention from CMHNs randomised to the HIP Programme group was disappointing at baseline despite their largely positive attitude towards a physical health care role, and at follow-up was far too low to allow the planned statistical analyses. This was mirrored in the low response rate for the adapted PHASe in nurse subjects. The trial phase found no evidence that CMHN facilitated health checks following HIP Programme training are effective at improving the physical wellbeing of patients on their caseload over 12 months.

The process observation phase provides some indication of why nurses who were motivated to enter the trial and held a largely positive attitude towards improving the physical wellbeing of their patients were unable to do so. Despite patients' expressing a wish for their CMHN to undertake their physical health care, nurses experienced barriers related to clinical engagement and organisation of their work and reported this impacted on their ability to intervene beyond assessment. These important results are broadly generalisable to patients with SMI and CMHNs working in generic and community mental health teams across England outside of major cities.

# Chapter Twelve: Impact of practice application of the HIP

Since the publication of the HIP development paper in 2009, I regularly received requests for HIP resources and reports from those who had attempted to implement it into practice. I specifically requested assurances that the resources I disseminated would not be shared with others without permission to avoid contaminating the trial. This chapter summarises the data either reported to me about the use of the HIP or published by others.

## Survey of HIP contacts

I sent PDFs of the HIP and HIP Manual to 72 people who contacted Professor Richard Gray or myself requesting copies and further information. I maintained an email contact group of these enquirers (after seeking their permission) and in 2013 I sent a short email invitation to an online survey about use of the HIP (using SurveyMonkey©). These contacts included mental health nurses, pharmacists, policy project officers and academics. Twenty percent of these contacts (n=14) were from outside the UK (Ireland, the Netherlands, Switzerland, Australia, New Zealand and the USA). Sixty-three contacts went on to complete the online survey representing a 63% response rate. Twenty six respondents (36%) reported using the HIP for research, education and/or to develop policy, practice or nurse education programmes. Nineteen respondents (26%) said they had used the HIP in clinical practice to support health checks in their organisations, completing at least one HIP with a total of 2450 patients.

### Care pathways and commissioning targets

Two nurses from the initial 2009 trainer cohort reported success in getting the HIP Programme embedded in their organisations as a standard for all patients. The HIP was adopted as the standard physical health risk assessment tool in NHS Lanarkshire in 2011 and is included in care pathways for adult mental health service users in North East Lincolnshire, Nottinghamshire, Northampton, South Gloucester, Hull and East Yorkshire.

In Nottinghamshire Healthcare NHS Trust the HIP is implemented via an integrated care pathway across all adult inpatient services. Two NHS Commission for Quality Innovation [CQUIN] targets identified the percentage number of patients to have a completed HIP and physical health care plan per quarter from the beginning of 2011. In the final quarter of 2012, 98.2% (n=2,821) had a completed HIP and 96.9% (n=2,783) patients had a physical health care plan, exceeding both local CQUIN targets and translating into 0.1% of the total income of the Trust (increasing to 1.5% in 2012-13). Four further provider organisations in England have adopted a similar CQUIN model (serving the populations of North East Lincolnshire, Northampton, South Gloucester and Hull & East Yorkshire). However, only in North East Lincolnshire does the target relate to community care. The service manager in the organisation that provides community adult mental health services

(Navigo) won the 2013 Medipex NHS Innovations Champion award for integration of their physical health in SMI service with primary care. In this service where nurse led CMHN clinics are located in primary health care centres the HIP is integrated into care and referral pathways and the electronic patient record system. http://www.medipex.co.uk/news/latest-news/medipex-nhs-innovation-awards-2013-winners-announced/ .

**The HIP in Primary Care**

The primary care version of the HIP [HIP-PC] is used across Hull, Northampton and NHS London. Dr Sheila Hardy, when working as a Nurse Consultant in Primary Care Mental Health adapted the HIP with permission into templates for all primary care IT systems (Hardy and Gray, 2010) A pilot project that supported practice nurses to deliver annual health checks for SMI through education and use of the HIP templates informed CQUIN targets in Northampton, winning the Nursing in Practice Award, 2013. The project was cascaded across Northamptonshire, Leicester, Nottingham, Norwich and NHS London (Hardy et al., 2014). Dr Hardy trained 21 GPs who are Clinical Commissioning Group [CCG] mental health leads as part of the NHS London Primary Care Mental Health Leadership Development Programme. Feedback from these GPs was that they intended to recommend use of the HIP-PC and resources across their CCGs. The HIP-PC and resources (including the manual) can be accessed at http://physicalsmi.webeden.co.uk/ signposted from the Royal College of Psychiatrists website as a recommended resource for primary care. (http://www.rcpsych.ac.uk/quality/nationalclinicalaudits/schizophrenia/nationalschizophreniaaudit/nasresources.aspx). Working with NHS England's National Clinical Director for Mental Health, Dr Hardy continues dissemination of this important strand of the HIP work.

I introduced the HIP to mental health and learning disability nurses employed to improve physical health checks in primary care by the Hull City Healthcare Partnership in late 2010. Templates for serious mental illness, dementia and learning disability were adapted from the SMI HIP by the team, with an innovative pre-screening form developed to be completed by patients and carers before their visit to the clinic to maximise consultation time. Templates were piloted in 10 general practices across the city to support the annual health checks of 713 patients (444 patients with SMI. 136 with LD and 133 with dementia). The process was well received by patients, carers, GPs, practice nurses and commissioners and the intention was to cascade this across all Hull CHP GP practices. However, the physical health in mental illness team was disbanded in 2013 when local services were reconfigured and staff redeployed into the Improving Access to Psychological Treatment [IAPT] teams.

### International and translated versions

In 2010 the HIP, the HIP Manual and Programme resources were translated into Swiss German, adapting to fit Swiss referral pathways and policies. In August 2011, I delivered a series of nurse workshops and a physical health care in SMI conference for 60 nurse leaders and educators from across Switzerland at the University of Bern through translators. One hundred and forty-six patients had the Gesundheitsförderungsprofil Psychiatrie [$GEP^{PSY}$] implemented in a pilot cohort of community and inpatients with SMI (Bänziger 2013).

Two hundred and seven patients had a HIP completed by their CMHN in Hong Kong in 2012 following adaptation and translation of the HIP Programme into Hong Kong Chinese [HKC-HIP] (Bressington et al., 2014). In this study fidelity to implementation of the HIP was maintained and at 12 months 71.5% (n=148) of the baseline patients had a repeat HIP completed with their nurse. At follow up there were statistically significant increases in self-reported levels of exercise and the numbers of prescriptions for diabetes. Some general positive trends in other cardiovascular risk parameters, including improvement in some health behaviours and the total numbers of medicines prescribed for physical comorbidities were reported. There was an unexpected increase in the mean waist circumference between groups, probably reflecting the inaccuracy of this measure in practice. As a result of the feasibility of the HIP Programme intervention demonstrated in this study in Hong Kong a grant has been awarded for a Cluster RCT of the HKC-HIP to begin later in 2015.

## Chapter Summary

While the HIP Cluster RCT was under development and then in progress the HIP, the HIP Manual and the training was widely disseminated to clinicians and academics who requested it and were not working in the clinical trial NHS sites. As a result by 2013 it was reported that 5,249 people with SMI had completed a HIP. The HIP became the focus of local commissioning for quality innovation targets in 6 provider organisations in England and 678 practice nurses were trained in primary care. Staff from12 countries worldwide have accessed the HIP and HIP resources (manual and training material) for adaptation/translation for their SMI populations.

## Chapter Thirteen: Synthesis

There was no vehicle to promote the education of registered mental health nurses in physical health care across the NHS in 2008. The clinical trial research that had taken place that tried to improve the physical wellbeing of people with SMI through nurse-led intervention relied on sponsorship from the pharmaceutical industry for specific 'add on' nurse roles in secondary care (Ohlsen et al., 2005, Smith et al., 2007b). There was no evidence that the service improvements implemented to date could be sustained or make a difference on a population level to people with SMI.

This programme of research started with the design of a pragmatic tool to support mental health nurses to care for the physical health needs of the SMI patients with who they had contact. The HIP identified the physical health parameters at most risk and what mental health nurses could measure in routine practice and recommended action to bring about positive change. We intended to use an adapted traffic light system (red or green) to indicate when additional monitoring or intervention was required. We based the included parameters on a literature review and the thresholds and interventions on published guidelines and standards. Space on the one-sided document led to choices about what to include and in what order based on our collective experience. On the whole we successfully designed a document that had an evidence base and (we thought) could be easily incorporated into the practice of individual nurses. Initial piloting was successful and the documents and training workshops designed to facilitate the use of the HIP in practice were very well received and evaluated by mental health nurses from across the UK. We published a paper about the development of the HIP Programme and were inundated with UK and international requests for copies of the HIP and training materials. I maintained a database of (email) contacts and shared resources with those who asked for them.

The case series in Scotland was pragmatic. The implementation of the HIP into the routine monitoring at a nurse-led clinic provided a sample where data had been entered into an excel database constructed by the nurse who ran the clinic. The organisation approved a service evaluation of this data, and an evaluation of the clinician and patient experience. The resulting published case series provided evidence of utility and acceptability. It also described considerable physical comorbidity (and therefore need) in the sample. This cross section of health status data highlighted how difficult it was to positively change physical parameters in people with SMI because these were patients that were already engaged in regularly attending a nurse led clinic for the management of their medication. I compared the clinic data with results of cohort studies into SMI patients in primary care and found similar levels of comorbidity. The extension of the service evaluation of HIP data to the two acute inpatient wards of the same hospital (the HIP-100) demonstrated much higher rates of comorbidity. It was therefore possible that attendance

at the clinic was already having a positive impact on patients' health outcomes (e.g. by supporting medicines adherence, by engaging patients in smoking cessation, by regular monitoring).

When writing the NIHR Research for Patient Benefit grant application for a clinical trial and the outline trial protocol within it I paid more attention to some aspects of the research design than others. So for example public and patient involvement, ethical issues, governance and the financial cost of conducting the research were addressed as was the feasibility of recruitment and retention. There was no requirement from the funders to demonstrate fidelity of the intervention i.e. if the intervention could be implemented as intended by CMHNs in their routine work, rather than in a clinic setting.

The trial demonstrated that the HIP Programme (training to use the HIP and an encouragement to use the HIP to support an annual health check in secondary care) did not improve patients physical health related quality of life at 12 months. It was disappointing that only around half the nurses in the HIP Programme group returned a copy of the HIP to the research team at baseline and just under a third at follow up. The assumption that CMHNs could easily adopt the HIP into their clinical work to change the health behaviour of SMI patients they worked with was not true.

**Does the HIP have utility?**

The evidence for utility of the HIP is strong. By 2013 over 5,000 patients in the UK had a HIP completed with their mental health nurse and at least 294 internationally. Five secondary care provider organisations in England and a health board in Scotland had adopted the HIP into standardised care pathways for adult patients admitted to secondary care. In two large NHS mental health provider Trusts, the use of the HIP was commissioned with completion within two weeks of admission, a Commissioning for Quality and Innovation [CQUIN] target. Reports suggest these targets have been achieved and often exceeded. The HIP has been adapted into a primary care, Swiss-German and Hong Kong Chinese versions. However, HIP completion rates do not tell us what use is made of the HIP data in terms of individualised physical care planning or health improvement over time.

Where organisations have attempted to expand the HIP into community services professional and organisational barriers have been highlighted including that not all patients have Care-Coordinators who are nurses, time (including time on caseload), caseload size, staff knowledge and skills deficits, lack of equipment /facilities and problems with secondary-primary care interface working. The only places in the UK where the HIP has been successfully implemented by CMHNs are in nurse-led clinics. The nurse prescriber led wellbeing clinics in the community enterprise company in North East

Lincolnshire (and their CMHTs) are co-located with primary care services in health centres. Co-location has the potential to facilitate joint working and may help to normalise access to mental health care and start to address stigma. It is intriguing that in a pilot study in Hong Kong, CMHNs used the HIP and were able to repeat it with SMI patients at a year, demonstrating a significant improvement in some metabolic risk parameters. It is not known if this has something to do with the culture and organisation of CMHN work in Hong Kong, or was a feature of their involvement in the research project.

**Is the HIP acceptable?**

There is evidence from the two case series and the HIP contact survey that having a physical health check with a mental health nurse using the HIP is acceptable to patients, clinicians and commissioners of services. In those organisations where the HIP is part of a CQUIN, data is entered into the HIP within the electronic patient record with drop down boxes, indicating green, amber (for increased frequency of monitoring) or red flags and a choice of intervention. The nature of the CQUIN target determines the focus of intervention on process outcomes (e.g. that all staff are trained, that HIP data is entered within two weeks of admission, that patients are satisfied with their physical health care), rather than health outcomes. In many acute inpatient services the HIP data entry takes place away from patients and risks the decision making part of the HIP being overlooked (i.e. the choices as a result of feedback on a parameter are not discussed and agreed with the patient). However the CQUINs have targets not just for completion but for intervention (usually those aligned to standards in the National Schizophrenia Audit and/or NICE Guidelines). Informal feedback from nurses who use the HIP every day and their managers are that problems are experienced with the database interface and the time limits imposed for data entry per patient (e.g. data cannot always be entered if the standard time for completion has passed). Despite these problems they report that the focus on physical health using the HIP is useful and means that physical health needs and interventions are discussed in sessions with patients and other disciplines with an increased emphasis on physical health in recovery (care) plans.

**Does the HIP work?**

The result of the trial does not mean that the HIP (form) does not work to assess physical health parameters, to indicate when they are out of range and intervention is needed or to help focus a collaborative care plan. The trial did not measure these outcomes. The trial results showed that the process of using the HIP (or knowledge from it) after the training intervention did not improve patients' health related quality of life over a year. Quality of life is the outcome required by NICE and is also necessary for economic analysis. The choice of the SF36v2 PCS for the primary outcome measure may not have been appropriate. It may not be specific enough (to SMI) or sensitive enough (to change over

12 months) in the SMI population. So far, no trials of health checks in any population have demonstrated improved quality of life outcomes.

The strength of the trial was that it tested the effectiveness of recommended best practice in a real world clinical setting. The trial was conducted with nurses that are typical of those working in community mental health services in England today. The trial was conducted to a high standard and was commended for its research governance processes following two sponsor audits. Robust procedures for maintaining researcher blinding were implemented and there were no breaches of this during the trial. In a population where attrition rates in clinical trials can be considerable, we achieved a 74% follow up at 12-months. This was particularly impressive given that we tightly defined timings for patient assessment, as patients had to be assessed within two weeks either side of the assessment due date.

Three aspects of treatment fidelity have been identified as important to the reliability and validity of studies of health behaviour change interventions: delivery of the intervention by the practitioner, receipt of the intervention and it's enactment (use) by the patient (Bellg et al., 2004). It is not possible to attribute a non-significant trial result to ineffectiveness of an intervention where fidelity is unknown. In the HIP Cluster RCT, considerable problems with delivery of the HIP by CMHNs were identified. Where a nurse completed the HIP as intended with a study patient, there was an assumption that the recommended action would take place and impact directly on patient health outcomes, including the primary outcome of the patient's perception of their physical health state.

The recently published mixed methods pilot study of the 'Traffic Light Method for Somatic Screening and Lifestyle' (TLM) in community and inpatients with SMI in the Netherlands demonstrated a significant reduction of patients body weight and waist circumference at three months (van Meijel et al., 2014). The intervention required 12 hour training of the four mental health nurses who delivered the intervention from one clinical nurse specialist, assessment using the TLM and three months of weekly 15 minute sessions (3.25 hours of intervention) and supervision (time not specified) from the same nurse specialist. The cost of this was covered by a specific grant. This is an example of a study where there has been considerable attention to the implementation of an evidence based health behaviour change intervention alongside health screening. However this approach relies heavily on the skills and knowledge of the clinical nurse specialist and the authors acknowledge the challenges in scaling up such an intervention into a research design that can test efficacy.

The HIP trial took place against a background of redesign of services, a third of CMHNs recruited into the study worked in assertive outreach teams that no longer existed at 12-month follow-up. Teams were reconfigured, caseloads dispersed or merged and/or patients discharged. Assertive outreach teams are more effective at engaging patients with SMI than generic community mental health teams, but no more effective in preventing

readmission to inpatient care (Killaspy et al., 2006). In times of austerity, commissioners may focus on short-term expensive outcomes such as preventing admission rather than health promotion that may take considerable time to result in measurable change. Physical health care has only recently been highlighted as a core competence of mental health nursing (Nursing and Midwifery Council, 2010b). Staff and managers have been observed to be less likely to adopt and prioritise new ways of working that breach existing organisational divisions and culture when they perceive services and teams to be under threat (Popay et al., 2004).

### Methodological challenges

Merely identifying which physical comorbidity parameters are at risk and requiring nurses to have the skills and ability within their work and workplace to engage and intervene to positively change these could be rightly criticised for being a naive approach to a complex issue. We just do not have the evidence of what is needed in this population to change these health behaviours (and for many of them little evidence how to change them in the general population). We have some limited evidence in some areas, for example, in smoking cessation and the management of weight gain in schizophrenia, but not in others, for example, the majority of metabolic outcomes, health outcomes in women with schizoaffective disorder (the most at risk). It appears we may have got methodologically ahead of ourselves in forging ahead with a clinical trial without establishing fidelity to or efficacy for individual aspects of the intervention.

The interventions in the HIP for the most part were based on guidelines and we know that guidelines alone do not change practice. Guidelines are supposedly based on the best available evidence but they do not usually indicate how the recommended action should be implemented. They tend to rely on the skills, motivation and confidence of the individual clinician, including their ability to work and communicate across multiple professional and service boundaries to achieve results. It is not unusual for healthcare improvements to be attempted through interventions aimed at the knowledge, routine and attitude of individual healthcare practitioners. This approach ignores systems factors that may act as barriers to implementation. Most of the attention to barriers when designing the HIP and the training to implement it were based around minimising barriers to nurses being able to access the HIP (e.g. designing a paper-based tool that was free to access). The HIP prompted intervention by highlighting risk and the recommended intervention but it relied on the individual nurse to make this happen with the patient and within their usual system. Barriers to implementation, and therefore the fidelity of MHNs using the HIP in their practice to change patient health behaviour were largely ignored. Nurses were asked to identify barriers to implementation of the HIP in the training workshops and to come up with ways of overcoming them themselves. It was implicit within the design of the

intervention that nurses could act as change agents and had the skills to make this happen.

Guidance on the development and evaluation of complex interventions includes the recommendation that enough preparatory work has been completed to be confident that the intervention can be delivered as intended (Medical Research Council, 2008). There is an increasing interest in implementation science as a way to improve the translation of evidence into the practice of healthcare professionals. This would tend to be the focus once an intervention has demonstrated efficacy (e.g. when an intervention has enough evidence to be recommended in practice guidance). However, attention to fidelity at the earliest stage of the design of the complex intervention is important. A process observation at an earlier stage in the design related to a small pilot in routine CMHN practice may have allowed us to identify strategies to overcome some of the barriers that were encountered in the trial phase.

The HIP Programme met the definition of a complex intervention because it relied on several interacting components to have an effect (Medical Research Council, 2008). These included the ability of the nurse to bring about change in the patient and the system of care and the ability of the patient to improve their health as a result. One of the key questions in evaluating complex interventions is how the intervention works and how aspects of the intervention exert their effect (Craig et al., 2008). The functional relationship between the components of a complex intervention and its outcomes are rarely described or reported (Michie et al., 2009). We did not investigate the various elements of the intervention as to their ability to bring about change in the patient. This meant it was not possible to identify weaknesses in this strategy and attempt to strengthen these within the design. So, for example, there was the assumption that CMHNs working in secondary care could order a range of blood tests but the process observation demonstrated this was not routine and often difficult to facilitate. In the training, the availability of vital signs equipment was commonly highlighted as a barrier by nurse subjects. To obtain this equipment required nurses to access a budget (through their manager) and make sure any purchase met specific medical equipment governance requirements. Once equipment was obtained, some nurses needed to find ways to develop (or refresh) their clinical skills to be able to use it. Patient and service factors were not targeted. So, for example, the HIP assumes that once abnormal weight is identified, the nurse has the required skills and knowledge (and access to appropriate interventions) to engage the patient in changing their diet and exercise behaviours.

There are well-documented barriers to implementation of interventions aimed at improving the health outcomes of people with SMI by medical and nursing staff and these have been identified at the patient, professional and systemic level (De Hert et al., 2011a) (Happell et

al., 2012, Robson et al., 2013). Interventions tailored to prospectively identify and address barriers are more likely to improve professional practice than no intervention or to dissemination of guidelines or educational materials alone (Baker et al., 2010).

Little is known about the ability of community mental health nurses to implement physical health interventions. A recent pilot project in Greater Manchester that focussed on training of key staff, leadership and methods to improve shared care across the primary-secondary care interface improved the availability of cardiovascular risk data for SMI patients in primary care (National Institute for Health Research Collaboration. for Leadership in Applied Health Research and Care (CLAHRC) for Greater Manchester, 2013). However use of the selected physical health check, the Rethink tool (Phelan et al., 2004), by Care-Coordinators was limited by a lack of clinical (nursing) skills amongst the multidisciplinary secondary care community workforce, low confidence in skills application and the time available to conduct the health check. These authors recommend targeting barriers to implementation through a boundary spanning role, knowledge integration, standardisation and a supportive organisational culture but other than appointment of primary-secondary care link workers did not identify what may be required to achieve these.

Implementation science is a relatively new area of health research but models and methodologies have been published that may help guide health researchers to better identify and target barriers to implementation. For example the normalisation model aims to help identify the factors that enable complex interventions to be embedded in routine clinical work (May, 2006). This appears particularly relevant to an intervention like the HIP programme because it was designed to support the implementation of complex interventions in chronic disease management and considers the work that needs to take place at a micro (between nurse and patient) and macro level (the organisational context).

Authors consistently identify patient, professional and organisational barriers to implementation of interventions in mental health services. Examples of all three were highlighted in the process observation: patient barriers included those related to motivation to change their own health behaviours and belief that this was possible, professional barriers included difficulties knowing how best to help patients change their health behaviours. Both of these could be addressed by more of an emphasis on motivational interviewing and problem solving approaches within the education of MHNs, and skilled supervision to build and maintain practice competence. Organisational barriers included the size of CMHNs caseload, the focus of the work they do and are used to (culture) and the way mental health and physical health services are organised and incentivised within the NHS. New ways of commissioning mental health care may provide

a way to break down the traditional ways of working and boundaries between services that act as barriers to true holistic care.

## Chapter summary

The problem of increasing morbidity and early mortality in the population of people with SMI remains. Targeting the mental health nurse as an agent of intervention to impact on these important health disparities at a population level has not yet been demonstrated to make a difference. There are some promising findings, from the TLM intervention and the Hong Kong Chinese-HIP (van Meijel et al., 2014, Bressington et al., 2014) and both of these are due to be tested in clinical trials. In primary care, there is, as yet, no evidence that targeting practice nurses or GPs to implement intervention makes a difference to health outcomes. However, it has been possible to increase the numbers of patients who receive health checks in secondary or primary care, with the implementation of training and (funded) resources (Smith et al., 2007b, Hardy et al., 2014, National Institute for Health Research Collaboration. for Leadership in Applied Health Research and Care (CLAHRC) for Greater Manchester, 2013). Contextual factors appear to be very important but have not yet been addressed. The Greater Manchester CLAHRC pilot study showed that where some attention is given to designing methods to support physical health care roles in CMHTs and promote integrated working, other factors continue to inhibit health checks. Future research should aim to specifically identify and target these barriers. This would appear to be best applied to one aspect of physical comorbidity in SMI where there is the most evidence of effect of the intervention.

## Conclusion and recommendations

The programme of work presented in this thesis included a systematic review, development of the HIP programme, two pragmatic case series, a pre and post training evaluation, a cluster randomised controlled trial, a process observation and a survey of contacts with whom HIP resources had been shared. The systematic review identified that despite evidence of a considerable knowledge and skills deficit in healthcare professionals working in secondary mental health services, information about how best to educate them to meet the physical healthcare needs of people with SMI was absent from the literature. A pragmatic tool and education intervention (the HIP Programme) was designed to address this deficit based on the available published evidence about health parameters and interventions in SMI and the authors' experience. An early case series in a convenience sample of community patients who were engaged in a nurse led SMI clinic in secondary care demonstrated utility of the intervention and considerably physical comorbidity in patients, with similar results but greater comorbidity in an acute in-patient sample from the same hospital. A comparison with primary care SMI data from a similar geographical area suggested the HIP was a reliable measure of comorbidity parameters in this population.

Mental health nurses consistently report a positive attitude towards a physical healthcare role in SMI, but state they require training to enable them to enact the role. Their perception of low baseline knowledge to inform physical health care practice in SMI was confirmed and significant knowledge gain immediately after HIP training demonstrated in 38 MHNs via a pre and post training evaluation. The results of the clinical trial demonstrated that the process of using the HIP (or knowledge from it) by CMHNs in routine practice after training did not improve patients' health related quality of life over a year. Fidelity to implementation of the intervention by the CMHNs randomised to the training was 42% at baseline and only 28% at a year, considerably weakening the inferences that could be drawn about effectiveness. The process observation immediately after the trial in a subsample of HIP group participants showed that despite patients' expressing a wish for their CMHN to undertake physical health care, nurses experienced barriers related to clinical engagement and organisation of their work. These barriers were reported to impact on their ability to intervene beyond assessment and/or repeat the HIP at a year.

The HIP is well liked by clinicians and patients and there is no evidence of any harm from its use. It continues to be used across the UK and internationally by nurses, services and commissioners of mental health services. A survey of 72 contacts with whom HIP resources had been shared indicated at least 5,000 people with SMI worldwide had their health checked using the HIP. The results of this entire programme of research do not

mean that the HIP (form) does not work to assess physical health parameters and indicate when intervention is needed or that the education package is not useful or appropriate. None of the research elements measured these outcomes. However, it does indicate that CMHNs cannot currently use the HIP in secondary mental health services in England to conduct annual health checks in patients with SMI on their caseloads to improve physical health related quality of life over the time frame of a year.

**Recommendations for practice, education, research and health policy**

Nurses should continue to use the HIP resources if they wish to support and develop their practice. MHNs working in community settings should consider implementation of a nurse-led clinic for patients with SMI to focus on physical health care that has a budget for staff training, equipment and health outcome measurement. Routine risk assessment in care pathways for people with SMI should include an assessment of the risk of cardiovascular disease and metabolic syndrome. Data should be routinely collected for all cardio-metabolic outcomes in SMI and care plans (including those under the Care Programme Approach) should be individualised to attempt to address and evaluate those parameters that are out of range. Mental health nurses should explore the potential of collaborative working with primary care including boundary spanning roles and co-location of clinics.

Low levels of physical health knowledge and the skills and confidence of MHNs in engaging patients in health behaviour change still needs to be addressed. The measurement of physical health parameters and engagement of patients in conversations about their health are identified by the professional regulatory body as essential skills for all nurses. The strategies used by educators and practice mentors to achieve and measure these are currently unknown, so should be investigated and disseminated. A longer period of generic nurse training before MHN field specialisation may help to address skills deficits in practice over time, but would depend on access to appropriate placements where the skills can be observed and then used under supervision to achieve competence. This depends on a workforce that is already using these skills. As these are likely to be limited in number, early implementers should be supported and nurtured. Peer networks should be initiated and used to enable learning from local projects to be shared. Commissioners should incentivise specific projects or education initiatives and the collection, reporting and evaluation of data so that outcomes can be rapidly disseminated.

We designed the trial without first testing that health checks in the SMI population are effective or examining fidelity to implementation of health checks using the HIP by CMHNs in their routine work. It could be argued that there is a case for testing individual elements of a health check before combining them and then carefully considering the clinical setting and organisational culture in which they are to be implemented. This should include

assessment of the readiness of the organisation and workforce to adopt the intervention and a scoping of the potential barriers and levers to success early on in the process.

Attention to the fidelity of the intervention (to include methods to enhance delivery, receipt and enactment) should be included in future research designs. Researchers in all areas of chronic disease management, comorbidity research and implementation science should combine their efforts to develop appropriate subjective and objective measures of health status in SMI and strengthen future research designs. It would also be prudent to explore the potential of nurse-led clinics and the benefits of co-location of secondary and primary care services for people with SMI.

Funders should incentivise research teams to attempt to address barriers to implementation by requiring these to be identified and methods to be included to address them in grant applications. Health policy writers should acknowledge the paucity of evidence for annual health checks in SMI and work to standardise a minimum set of physical health outcome data to enable evaluation of future initiatives to improve health and reduce mortality in this population. The National Schizophrenia Audit could be expanded to enable this by including data from people with a diagnosis of schizoaffective or bipolar disorder. Mental health provider organisations should routinely investigate any death that occurs in patients with SMI under their care where the cause of death is “natural” and this data should be reported and investigated at a local, regional and national level to afford deaths due to physical comorbidity in SMI as much attention as death by suicide. NICE should revise its recommendations about health checks in SMI to reflect the current state of research evidence.

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