

Appendix 1

HIP Male and Female

Participant ID _____		Other information _____		Date of birth (age) _____	
Ethnic Classification _____		Weight _____		Height _____	
Date _____					
Parameter	Level	Green	Red	Recommended action for red group	
BMI		18.50-24.99 ¹	< 18.50 ¹ ≥ 25.00* ¹	<input type="checkbox"/> BMI < 18.50 – refer for further investigations <input type="checkbox"/> BMI ≥ 25.00 – advice and support on diet and exercise, referral to local weight/exercise management programme, consider medication review ²	
Waist Circumference		< 80cm ³	≥ 80cm ³	<input type="checkbox"/> Advice and support on diet and exercise, referral to local weight/exercise management programme, consider medication review ²	
Pulse		60 – 100bpm ⁴	< 60 bpm / > 100bpm	<input type="checkbox"/> ECG should be performed ⁴	
Blood Pressure		< 140/90 ⁵	≥ 140/90 ⁵	<input type="checkbox"/> Advice on weight loss (if overweight) and increased activity, reduction in alcohol intake, improved diet and smoking cessation ⁵ <input type="checkbox"/> Refer to GP for further investigations ⁵	
Temperature		36-37.5°C ⁶	< 36 °C ⁷ > 37.5°C ⁷	<input type="checkbox"/> Abnormally high and accompanied by fluctuating BP and/or dystonia consider neuroleptic malignant syndrome <input type="checkbox"/> Report to RMO, refer for further investigations ⁶	
Liver function (in last 3 months)		≤ 3 months	> 3 months	<input type="checkbox"/> Ensure that up-to-date LFTs are conducted <input type="checkbox"/> Abnormal – refer for further investigations ⁸ <input type="checkbox"/> Slightly abnormal (> 2 times ULN) – repeat tests in 6 months time, check alcohol intake, diabetes control and weight loss ⁸ <input type="checkbox"/> Consider medication review ⁹	
Lipid Levels ³		TC < 5.1 mmol/L LDL – C < 4.1 mmol/L HDL – C > 1.3 mmol/L TG < 2.2 mmol/L ²	TC ≥ 6.2 mmol/L LDL – C ≥ 4.1 mmol/L HDL – C < 1.3 mmol/L or TG ≥ 2.2 mmol/L ²	<input type="checkbox"/> Refer to GP for appropriate treatment ²	
Glucose		< 11.1 mmol/L†§ ³⁵ < 6.5% (48 mmol/mol)†§ ³⁵ < 7.0 mmol/L†§ ³⁵	≥ 11.1 mmol/L†§ ³⁵ ≥ 6.5% (48 mmol/mol)†§ ³⁵ ≥ 7.0 mmol/L†§ ³⁵	<input type="checkbox"/> Check for symptoms of diabetes ² <input type="checkbox"/> Test for urine ketones if symptoms are present ² <input type="checkbox"/> Refer for further investigations and treatment ²	
Cervical smear		≤ 3 years (aged 25-64) ≤ 5 years (aged 50-64) ¹¹	> 3 years (aged 25-64) ¹¹ > 5 years (aged 50-64) ¹¹	<input type="checkbox"/> Refer to GP or specialist practice nurse ¹¹	
Sleep		7 – 8 hours ¹²	< 3 hours ¹² > 8 hours ¹²	<input type="checkbox"/> Clarify sleep problem <input type="checkbox"/> Provide education on good sleep hygiene and benefits of a sleep diary <input type="checkbox"/> Consider medication review <input type="checkbox"/> Refer if relapse is suspected (refer to Risk and Relapse Plan and take action accordingly)	
Teeth		≤ 12 months ¹³	≥ 2 years ¹³	<input type="checkbox"/> Encourage regular visits to community dentist ¹³	
Eyes		< 2 years ¹⁴	> 2 years ¹⁴	<input type="checkbox"/> Prompt to self refer/refer to optometrist if no eye exam in last 2 years	
Feet		Self check occasionally	Never check	<input type="checkbox"/> Advice on keeping feet healthy ¹⁵ <input type="checkbox"/> Elderly patients/those with diabetes – refer to chiropodist ¹⁵ <input type="checkbox"/> If any presenting signs/symptoms – refer to chiropodist	
Breast		Self-check monthly / routine breast screenings	Never check	<input type="checkbox"/> Advice on self-examination ¹⁶ <input type="checkbox"/> Patients 50-70 years refer for breast screening (repeat every 3 years) ¹⁶ <input type="checkbox"/> Breast abnormalities – refer for further investigations ¹⁷	
Menstrual cycle		Regular 28 day ovulation cycle (range:24-35 days) ¹⁸	Irregular/Absent/Reduced/Excessive ¹⁹	<input type="checkbox"/> Refer for further investigations	
Smoking status		Non smoker	Passive smoker / smoker	<input type="checkbox"/> Advice that all smoking is associated with significant health risks ²⁰ <input type="checkbox"/> Refer to NHS Stop Smoking Services ²⁰ ++	
Exercise		30 minutes a day	None	<input type="checkbox"/> Recommend 30 minutes of activity 5 days a week ²¹ <input type="checkbox"/> Follow up on a 3-6 monthly period ²¹ <input type="checkbox"/> Refer to exercise referral scheme if required ²¹	
Alcohol intake		2-3 units/day†‡ ²²	> 3 units/day ²²	<input type="checkbox"/> Offer recommendations on sensible daily alcohol intake ²² (guide to alcohol units ²³)	
Diet: 5 a day ^a		5 portions a day §§ ²⁴	≤ 2 portions a day ²⁴	<input type="checkbox"/> Offer recommendations on reduction of health risks with 5-a-day ²⁴ <input type="checkbox"/> Address potential barriers to accessing and eating fruit/vegetables ²⁴ <input type="checkbox"/> Agree and implement a plan with the patient (and carers if appropriate) <input type="checkbox"/> May include referral to other members of the MDT e.g. occupational therapist for meal planning, shopping and cooking skills	
Diet: Fat intake ^a		≤ 1 portion***a day	≥ 2 portions a day	<input type="checkbox"/> Agree and implement a plan with the patient (and carers if appropriate) <input type="checkbox"/> May include referral to other members of the MDT e.g. occupational therapist for meal planning, shopping and cooking skills	
Fluid intake		1-2 litres/day ²⁵	< 1litre/day ²⁵ > 3 litres/day ²⁶	<input type="checkbox"/> < 1 litre/day – check for signs of dehydration ²⁵ <input type="checkbox"/> Offer advice on increasing fluid intake ²⁵ <input type="checkbox"/> > 3 litres/day – check for signs of polydipsia ²⁶ <input type="checkbox"/> Implement a fluid balance chart <input type="checkbox"/> Refer for electrolyte assessment if initial intervention unsuccessful	
Caffeine intake ^a		200-500 mg/day ²⁷ †††	≥ 600mg/day ²⁷	<input type="checkbox"/> Check for signs of caffeineism or caffeine toxicity (> 1000 mg/day) ²⁷ <input type="checkbox"/> Offer advice to gradually reduce caffeine intake and limit withdrawal effects ²⁷	
Cannabis use		Never	Occasional/Regular	<input type="checkbox"/> Implement health behaviour interventions and evaluate <input type="checkbox"/> Work with support of dual diagnosis worker/service <input type="checkbox"/> Systemically evaluate action e.g. using a Drug Use Scale	
Safe sex		Always	Inconsistently/Never	<input type="checkbox"/> Identify if patient is in high risk group for STIs ²⁸ <input type="checkbox"/> Identify if patient is engaging in behaviours that increase risk of STIs ²⁸ <input type="checkbox"/> Provide sexual health advice <input type="checkbox"/> If STI suspected refer to GP or sexual health practice nurse ²⁸	
Urine		1-2 litres/day ²⁹	< 1litre/day ²⁹ > 2litres/day ³⁰	<input type="checkbox"/> Assess for signs of dehydration ²⁹ <input type="checkbox"/> Assess for symptoms of polyuria ³⁰ <input type="checkbox"/> Check for any urine frequency/incontinence issues <input type="checkbox"/> Encourage fluids and implement fluid balance chart to evaluate	
Bowels		No constipation / diarrhoea No excessive urgency/straining/need for laxatives ³¹	Diarrhoea, constipation, excessive urgency, straining, laxative use ³¹	<input type="checkbox"/> Encourage fluids <input type="checkbox"/> Check for gastrointestinal symptoms <input type="checkbox"/> Check for any bowel urgency/incontinence issues <input type="checkbox"/> Refer for further investigations	
Sexual satisfaction		Satisfied	Dissatisfied	<input type="checkbox"/> Perform systemic assessment (e.g. Arizona Sexual Experience Scale) of the health parameter <input type="checkbox"/> Refer for gynaecological investigations/laboratory assessments ³²	

^aWhere results fall between red and green ranges, increase frequency of monitoring and review. ¹Overweight=BMI>23.00 in individuals of South Asian origin. ²†BMI for Europids – refer to ethnic-specific values where required. ³§ Oral glucose tolerance test. Fasting plasma glucose. ⁴Ø glycated haemoglobin. ⁵Random venous plasma glucose. ⁶††Warning – careful planning/medication review is required if smoking cessation planned. MHN to identify this need. ³³†††Pregnant women should avoid drinking alcohol, if they do choose to drink, they should not drink more than 1-2 units once or twice a week. ³⁵Five portions of a variety of fruit and vegetables. ³⁶A portion of food high in saturated fat or trans fat (e.g. meat products, hard cheese, butter/lard, pastry, cakes / biscuits, cream). Total fat considered high if more than 20g fat per 100g. ³⁷†††Average caffeine content – 1 cup of coffee = 75-100mg; 1 cup of tea = 50mg; 1 can of cola = 40mg; 1 energy drink = 90mg; bar of plain chocolate = 50mg; bar of milk chocolate = 25mg. ³⁴BMI – body mass index, ECG – electrocardiogram, HDL-C – high density lipoprotein – cholesterol, LDL-C – low density lipoprotein – cholesterol, STI – sexually transmitted infection, TC – total cholesterol, TG triglycerides, ULN – upper limit of normal.

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Participant ID _____ Other information _____ Date of birth (age) _____

Ethnic Classification _____ Weight _____ Height _____ Date _____

Parameter	Level	Green	Red	Recommended action for red group
BMI		18.50-24.99 ¹	< 18.50 ¹ ≥ 25.00 ^{1*}	<input type="checkbox"/> BMI < 18.50 – refer for further investigations <input type="checkbox"/> BMI ≥ 25.00 – advice and support on diet and exercise, referral to local weight/exercise management programme, consider medication review ²
Waist Circumference		<94cm ¹³	≥94cm ¹³	<input type="checkbox"/> Advice and support on diet and exercise, referral to local weight/exercise management programme, consider medication review ²
Pulse		60 – 100bpm ⁴	<60 bpm/> 100bpm	<input type="checkbox"/> ECG should be performed ⁴
Blood Pressure		<140/90 ⁵	≥140/90 ⁵	<input type="checkbox"/> Advice on weight loss (if overweight) and increased activity, reduction in alcohol intake, improved diet and smoking cessation ⁵ <input type="checkbox"/> Refer to GP for further investigations ⁵
Temperature		36-37.5°C ⁶	<36 °C ⁷ >37.5°C ⁷	<input type="checkbox"/> Abnormally high and accompanied by fluctuating BP and/or dystonia consider neuroleptic malignant syndrome <input type="checkbox"/> Report to RMO, refer for further investigations ⁶
Liver function (in last 3 months)		≤ 3 months	> 3 months	<input type="checkbox"/> Ensure that up-to-date LFTs are conducted <input type="checkbox"/> Abnormal – refer for further investigations ⁸ <input type="checkbox"/> Slightly abnormal (> 2 times ULN) – repeat tests in 6 months time, check alcohol intake, diabetes control and weight loss ⁸ <input type="checkbox"/> Consider medication review ⁹
Lipid Levels		TC < 5.1 mmol/L LDL – C < 4.1 mmol/L HDL – C > 1.0 mmol/L TG < 2.2 mmol/L ²	TC ≥ 6.2 mmol/L LDL – C ≥ 4.1 mmol/L HDL – C < 1.0 mmol/L or TG ≥ 2.2 mmol/L ²	<input type="checkbox"/> Refer to GP for appropriate treatment ²
Glucose		< 11.1 mmol/L ^{13,33} < 6.5% (48 mmol/mol) ³³ < 7.0 mmol/L ³³	≥ 11.1 mmol/L ^{13,33} ≥ 6.5% (48 mmol/mol) ³³ ≥ 7.0 mmol/L ³³	<input type="checkbox"/> Check for symptoms of diabetes ² <input type="checkbox"/> Test for urine ketones if symptoms are present ² <input type="checkbox"/> Refer for further investigations and treatment ²
Prostate and testicles		Once a month (testicular self examination)	Never	<input type="checkbox"/> Confirm prostate screening at fixed intervals for patients over 50 years ¹² <input type="checkbox"/> No recent PSA test – refer to GP or specialised practice nurse
Sleep		7 – 8 hours ¹³	< 3 hours ¹³ > 8 hours ¹³	<input type="checkbox"/> Clarify sleep problem <input type="checkbox"/> Provide education on good sleep hygiene and benefits of a sleep diary <input type="checkbox"/> Consider medication review <input type="checkbox"/> Refer if relapse is suspected (refer to Risk and Relapse Plan and take action accordingly)
Teeth		≤ 12 months ¹⁴	≥ 2 years ¹⁴	<input type="checkbox"/> Encourage regular visits to community dentist ¹⁴
Eyes		≤ 2 years ¹⁵	> 2 years ¹⁵	<input type="checkbox"/> Prompt to self refer/refer to optometrist if no eye exam in last 2 years
Feet		Self check occasionally	Never check	<input type="checkbox"/> Advice on keeping feet healthy ¹⁵ <input type="checkbox"/> Elderly patients/those with diabetes – refer to chiropodist ¹⁶ <input type="checkbox"/> If any presenting signs/symptoms – refer to chiropodist
Breast		Self-check occasionally	Never check	<input type="checkbox"/> Check risk factors for male breast cancer (i.e. previous radiotherapy, obesity, family history of breast cancer, high oestrogen levels or chromosomal syndromes) ¹⁷ <input type="checkbox"/> Breast abnormalities – refer for further investigations ¹⁷
Smoking status		Non smoker	Passive smoker / smoker	<input type="checkbox"/> Advice that all smoking is associated with significant health risks ¹⁸ <input type="checkbox"/> Refer to NHS Stop Smoking Services ^{18,58}
Exercise		30 minutes a day ¹⁹	None	<input type="checkbox"/> Recommend 30 minutes of activity 5 days a week ¹⁹ <input type="checkbox"/> Follow up on a 3-6 monthly period ¹⁹ <input type="checkbox"/> Refer to exercise referral scheme if required ¹⁹
Alcohol intake		3-4 units/day ²⁰	>4 units/day ²⁰	<input type="checkbox"/> Offer recommendations on sensible daily alcohol intake ²⁰ (guide to alcohol units ²¹)
Diet: 5 a day ^a		5 portions a day ^{19,22}	≤ 2 portions a day ²²	<input type="checkbox"/> Offer recommendations on reduction of health risks with 5-a-day ²² <input type="checkbox"/> Address potential barriers to accessing and eating fruit/vegetables ²² <input type="checkbox"/> Agree and implement a plan with the patient (and carers if appropriate) <input type="checkbox"/> May include referral to other members of the MDT e.g. occupational therapist for meal planning, shopping and cooking skills
Diet: Fat intake ^a		≤ 1 portion ⁵⁹ a day	≥ 3 portions a day	<input type="checkbox"/> Advice on reducing fat intake and achieving a well-balanced diet <input type="checkbox"/> Agree and implement a plan with the patient (and carers if appropriate) <input type="checkbox"/> May include referral to other members of the MDT e.g. occupational therapist for meal planning, shopping and cooking skills
Fluid intake		1-2 litres/day ²³	< 1litre/day ²³ > 3 litres/day ²⁴	<input type="checkbox"/> < 1 litre/day – check for signs of dehydration ²³ <input type="checkbox"/> Offer advice on increasing fluid intake ²³ <input type="checkbox"/> > 3 litres/day – check for signs of polydypsia ²⁴ <input type="checkbox"/> Implement a fluid balance chart <input type="checkbox"/> Refer for electrolyte assessment if initial intervention unsuccessful
Caffeine intake ^a		200-500 mg/day ^{25,***}	≥ 600mg/day ²⁵	<input type="checkbox"/> Check for signs of caffeineism or caffeine toxicity (> 1000 mg/day) ²⁵ <input type="checkbox"/> Offer advice to gradually reduce caffeine intake and limit withdrawal effects ²⁵
Cannabis use		Never	Occasional/Regular	<input type="checkbox"/> Implement health behaviour interventions and evaluate <input type="checkbox"/> Work with support of dual diagnosis /service <input type="checkbox"/> Systemically evaluate action e.g. using a Drug Use Scale
Safe sex		Always	Inconsistently/Never	<input type="checkbox"/> Identify if patient is in high risk group for STIs ²⁶ <input type="checkbox"/> Identify if patient is engaging in behaviours that increase risk of STIs ²⁶ <input type="checkbox"/> Provide sexual health advice <input type="checkbox"/> If STI suspected refer to GP or sexual health practice nurse ²⁶
Urine		1-2 litres/day ²⁷	< 1litre/day ²⁷ > 2litres/day ²⁸	<input type="checkbox"/> Assess for signs of dehydration ²⁷ <input type="checkbox"/> Assess for symptoms of polyuria ²⁸ <input type="checkbox"/> Check for any urine frequency/incontinence issues <input type="checkbox"/> Encourage fluids and implement fluid balance chart to evaluate
Bowels		No constipation / diarrhoea No excessive urgency/ straining/need for laxatives ²⁹	Diarrhoea, constipation, excessive urgency, straining, laxative use ²⁹	<input type="checkbox"/> Encourage fluids <input type="checkbox"/> Check for gastrointestinal symptoms ²⁹ <input type="checkbox"/> Check for any bowel urgency/incontinence issues <input type="checkbox"/> Refer for further investigations
Sexual satisfaction		Satisfied	Dissatisfied	<input type="checkbox"/> Determine patient's level of sexual activity ³⁰ <input type="checkbox"/> Perform systemic assessment (e.g. Arizona Sexual Experience Scale) of the health parameter

^aWhere results fall between red and green ranges, increase frequency of monitoring and review. *Overweight = BMI > 23.00 in individuals of South Asian origin. ²¹BMI for Europids – refer to ethnic – specific values where required. ^{5*}Oral glucose tolerance test. Fasting plasma glucose. Ø glycosated haemoglobin. [†]Random venous plasma glucose. ¹⁴Warning – careful planning/medication review is required if smoking cessation planned. MHN to identify this need. ^{31,41}Five portions of a variety of fruit and vegetables. ⁵⁹A portion of food high in saturated or transfat (e.g. meat products, hard cheese, butter/lard, pastry, cakes/biscuits, cream). Total fat considered high if more than 20g fat per 100g. ***Average caffeine content – 1 cup of coffee = 75 – 100mg; 1 cup of tea = 50mg; 1 can of cola = 40mg; 1 energy drink – 90mg; bar of plain chocolate = 50mg; bar of milk chocolate = 25mg. ²³BMI – body mass index, ECG – electrocardiogram, HDL-C – high density lipoprotein – cholesterol, LDL-C – low density lipoprotein – cholesterol, STI – sexually transmitted infection, TC – total cholesterol, TG – triglycerides, ULN – upper limit of normal.

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Appendix 2
HIP Manual – v3

The serious mental illness Health Improvement Profile [HIP] Manual

Jacquie White

Sheila Hardy

Professor Richard Gray

Foreword

Physical illness in people with serious mental illness such as schizophrenia and bipolar disorder reduces life expectancy by up to 20 years. We think mental health nurses (MHNs) are well placed to help patients recognise and address physical health problems for example by helping them consider lifestyle changes such as diet, smoking, and exercise. However MHNs say they lack knowledge and skills about physical health to do this work effectively. We have developed a tool - the Health Improvement Profile [HIP] to help MHNs work with patients to profile their physical health, identify problems and choose what action to take. The HIP is gender specific and measures 28 aspects of physical health.

Norfolk and Waveney Mental Health Foundation NHS Trust (NWMHFT) is sponsoring research into the HIP funded by a National Institute of Health Research, Research for Patient Benefit grant and led by my research team at the University of East Anglia. This is the first randomised controlled trial of a nurse led physical health tool for serious mental illness in the UK. This manual is designed to provide additional information to help you use the HIP in your practice, following your attendance at the HIP training workshop.

Richard Gray
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The Health Improvement Profile (HIP) Manual

Introduction

Severe mental illness such as schizophrenia and bi-polar disorder is associated with high medical co-morbidity; mortality rates are approximately 50% higher than in the general population (Brown 1997). The primary cause of death due to a physical cause is circulatory disease, diabetes and obesity. Evidence suggests excess weight gain can be 2-3 times more prevalent in people with schizophrenia than in the general population (Allison and Casey 2001). This may be due to high levels of smoking, unhealthy diets and lack of exercise which are common lifestyle choices of people with schizophrenia (McCreadie 2003), and that antipsychotic medication can also exacerbate weight gain (Allison and Casey 2001).

The National Institute for Clinical Excellence (Nice 2009, 2006a) recommends that physical health checks should normally be provided within primary care but if the patient is not in contact with primary care then secondary services (the Mental Health Team) should monitor physical health (Nice 2009, 2006a). The Sainsbury Centre for Mental Health (2003) advocates that a physical health review should include advice about diet, exercise, smoking and substance and alcohol abuse; protection against influenza, plus regular preventative care.

The serious mental illness Health Improvement Profile [HIP] (White *et al.* 2009) is a specific tool designed to help mental health nurses outline the physical health of the SMI patients they work with and direct them towards the evidence base interventions available to address identified health problems. This includes using the opportunity of the HIP process and conversation with the patient and/or their carer(s) to exchange lifestyle advice.

A rationale and recommended action has been specified for each intervention. Unlike other tools such as the Physical Health Check (PHC) (Rethink 2008a), it is recommended that clinicians carrying out health checks using the HIP have attended a HIP training workshop.

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How to use the HIP and the HIP Manual

28 Parameters

The HIP is gender specific and measures 28 aspects of physical health identified at most at risk in serious mental illness (Robson & Gray, 2007):

HIP Parameters

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

The HIP has been designed to provide all the information required for a physical health check on one side of one page of the form for each patient. 28 HIP parameters are listed for each gender.

Green or red?

Each HIP parameter has a column for recording the result or 'level', followed by a column indicating the healthy 'green' range. The next column indicates the unhealthy 'red' range (requiring action) and a the final column indicates the recommended action if the parameter falls into the 'red' range.

e.g. the Temperature parameter looks like this:

Parameter	Level	Green		Red		Recommended action for red group
Temperature		37°C ⁶		<37°C ⁷ >37°C ⁷		<input type="checkbox"/> Abnormally high and accompanied by fluctuating BP and/or dystonia consider neuroleptic malignant syndrome <input type="checkbox"/> Report to RMO, refer for further investigations ⁶

Next steps when a parameter flags red

When a parameter flags red, the final column provides evidence-based information about the best next steps to take to inform your discussion with the patient (and carer(s) if appropriate) to agree a plan of care.

How often to complete a HIP

Physical health screening should take place at least once a year according to NICE, however you may choose to repeat the HIP or specific parameter items more often:

- if a parameter is at the upper limit of normal
- to allow an evaluation of action agreed with the patient at an agreed time interval
- to provide data to inform a treatment or CPA review

Referrals

If you select a referral as the best next step to take (e.g. to the patient's GP) we recommend you include a copy of the HIP with your referral letter.

Recording the HIP

The HIP has been designed to allow a copy of the HIP to be provided for the patient, for the patient's record and for the patient's GP (to allow them to update the primary care record). In the trial we will also ask you to send a fourth copy to the research team.

HIP Resource Use Questionnaire

In the HIP trial we want to find out about the resource implications of the HIP so we would be grateful if you could also complete and return a HIP Resource Use Questionnaire with a copy of the HIP to the research team every time you use one. These are included in your HIP pack. If you require additional forms please contact the research team (see page 44 for contact details).

Clinical skills

If you have any concerns about your physical examination skills (e.g. it may have been some time since you took a blood pressure and you may feel you lack confidence) please discuss your training needs in the usual way in supervision with your line manager so appropriate training and support can be identified and accessed.

Using the manual

Each HIP form is designed to provide information to support your clinical decision about what next steps to take and it includes references. The HIP Manual provides some additional detail on each of the HIP parameters and some of the additional tests which may be chosen as next steps/or already occur within local protocols or care pathways.

Measurements

Body Mass Index (BMI)

Rationale

Evidence suggests excess weight gain can be 2-3 times more prevalent in people with schizophrenia than in the general population (Allison and Casey 2001).

The BMI is a simple index used to determine whether an individual is underweight, overweight or obese (WHO 2006).

The BMI is defined as the weight divided by the square of the height. For example, a person who weighs 70 kg and has a height of 1.75 will have a BMI of 22.9.

A BMI calculator can be found at:

www.eatwell.gov.uk/healthydiet/healthyweight/bmicalculator/

Although BMI values are the same for both sexes, they may not be accurate in people who are athletes or who weight-train, in pregnant or breastfeeding women, or those over the age of 60 years.

Ethnicity should be considered, particularly in patients of South Asian origin (overweight varies from BMI > 23, obesity from BMI > 25).

Recommended action

Treatment or information exchange about weight loss should be offered to patients with:

- A BMI ≥ 30
- A BMI ≥ 28 with co-morbidities (eg coronary heart disease, diabetes)
- Any degree of overweight coinciding with diabetes or other serious diseases
- Families with more than one obese or overweight member
- Intervention should be offered to high-risk patients (eg those with learning disabilities, smokers, low income groups), before the BMI increases / or regardless of their BMI

Waist circumference

Rationale

The measurement of waist circumference provides information on the distribution of body fat (Lean *et al.* 1998). Waist circumference correlates with visceral adipose tissue (Pouliot *et al.* 1994, Taylor *et al.* 1998), plasma lipids, lipoproteins and insulin levels (Taylor *et al.* 1998), better than waist-to-hip ratio (WHR) in adults. People who carry their excess fat centrally (within the abdominal cavity) are more likely to suffer the consequences of being overweight.

When measuring waist circumference, you need to ensure that a tape of adequate length is available. The correct position for measuring waist circumference is midway between the upper hip bone and the uppermost border of the right iliac crest. The

tape should be placed around the abdomen at the level of this midway point and a reading taken when the tape is snug but does not compress the skin. In practice it may be difficult for very overweight patients to accurately palpate those bony landmarks in which case placing the tape at the level of the belly button is recommended (National Obesity Forum).

Recommended action

For patients with waist circumference ≥ 80 cm (female) / ≥ 94 cm (male) (Barnett *et al.* 2007):

- Support and exchange information on diet (ie meal planning) and exercise
 - Referral to a local weight/exercise management programme may be required
 - Consider medication review
-

Pulse rate

Rationale

Tachycardia (rapid pulse) is a common side effect of antipsychotic medications (Flanagan 2008). Prolonged untreated tachycardia places increased demands on the heart and could result in ischaemic heart disease, heart failure, myocardial infarction or even sudden cardiac death.

A resting heart rate anywhere in the range of 60 - 90 is considered in the normal range. However, many athletes have pulse rates in the 40 - 60 range. The heart rate will fluctuate a lot depending on such factors as a person's activity level and stress level (NEMA 2003).

Recommended action

Tachycardia caused by anticholinergic effects without postural hypotension can be managed with a low dose of peripherally acting β -blockers (Young *et al.* 1998). Pulse should be checked annually.

An ECG should be performed on all patients with an increased pulse. Where possible an ECG should be carried out on all patients taking antipsychotic medication due to the potential lengthening of the QT interval (exceptions are aripiprazole and quetiapine). Carrying out an ECG also allows the opportunity to look for other possible problems such as gynaecomastia, hygiene neglect and rashes.

The Committee for Proprietary Medicinal Products (CPMP 1997) divide subjects into three groups based on QTc interval length. For males, QTc values less than 430ms are normal, between 431 and 450ms are borderline and over 450ms are prolonged. For females QTc values less than 450ms are normal, between 451 and 470ms are borderline and over 470ms are prolonged. Patients with an abnormal ECG may be referred to a cardiologist or to the original prescriber for review of their treatment as appropriate.

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Blood pressure

Rationale

The British Hypertension Society Guideline cites evidence that suboptimal blood pressure control leaves patients at an unacceptably high risk of cardiovascular complications and death, particularly from coronary heart disease (CHD) but also from stroke (Williams *et al.* 2004).

Recommended action

- For patients with blood pressure > 140/90 mmHg, exchange information on weight loss/exercise (if overweight), improved diet and reduction in alcohol and salt intake and refer to the GP for further investigation.
- Interventions actively combining exercise and diet have demonstrated a reduction of both systolic and diastolic blood pressure by only 4–5 mmHg (NICE 2006b)
- If the patient's blood pressure is > 160/100mmHg or if it is over 140/90mmHg and they have diabetes or established cardiovascular disease, then the British Hypertension Society recommends that drug therapy should be started (Williams *et al.* 2004)

A note about cardiovascular risk and metabolic syndrome

The metabolic syndrome is a constellation of abnormalities that is associated with increased risk for the development of type 2 diabetes and cardiovascular disease (e.g., heart disease and stroke). The International Diabetes Federation consensus worldwide definition of the metabolic syndrome (2006) includes:

1. Central obesity (defined as waist circumference)

AND any two of the following:

2. Raised triglycerides
3. Reduced HDL cholesterol
4. Raised blood pressure
5. Raised fasting plasma glucose or previously diagnosed type 2 diabetes.

Primary prevention should be considered for all patients between 40-74 yrs with a high CVD risk (NICE 2008). The HIP recommends a GP referral when any of these blood test parameters flag red. The GP will calculate and confirm CVD risk using a scoring system such as the QRISK®2 (Hippisley-Cox *et al.* 2008). Simvastatin 40mg (or drug of similar efficacy and cost) for adults >40 years with 10-year CVD risk ≥20% should be offered (NICE 2008).

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Temperature

Rationale

Neuroleptic malignant syndrome is a rare but potentially life-threatening individual reaction to neuroleptic drugs. It causes fever, muscular rigidity, altered mental status and autonomic dysfunction. It is usually associated with potent neuroleptics such as haloperidol and fluphenazine. The underlying pathological abnormality is thought to be central D2 receptor blockade or dopamine depletion in the hypothalamus and nigrostriatal/spinal pathways. This leads to an elevated temperature set point, impairment of normal thermal homeostasis and extrapyramidally-induced muscle rigidity (Patient UK 2006a).

Other causes of a raised temperature include infection, heat stroke, alcohol withdrawal, anticholinergic drugs, allergic drug reaction, and agonist drugs (Dougherty and Lister 2004).

Recommended action

- Look for signs of infection and treat as appropriate
 - Ask about alcohol withdrawal
 - Check drug use
 - For abnormally high temperatures with a fluctuating blood pressure and/or dystonia consider neuroleptic malignant syndrome and refer urgently to medics.
-

Blood tests

It is useful to have a protocol stating which blood tests need to be taken for each care pathway. This allows other practitioners to offer these tests opportunistically to patients who may not have been well enough to accept them on admission.

Blood tests as part of the HIP

Liver Function Tests (LFTs)

Rationale

Antipsychotic medication can result in abnormal LFTs (Garcia-Unzueta *et al.* 2003). Hepatic disease should be detected early to prevent further serious complications.

Recommended action

Ensure LFTs are up-to-date or planned.

If tests are slightly abnormal:

- Repeat tests in 6 months
- Check alcohol intake and reduce if necessary
- Exchange information on diabetes control and weight loss if appropriate
- If remains abnormal for longer than six months then consider referral to a specialist
- If the patient is unwell despite slightly abnormal LFTs then they may need to be referred more urgently
- Very abnormal liver function tests (i.e. more than twice upper limit of abnormal):
 - Refer to GP to enable:
 - Organisation of further blood tests and imaging.
 - Referral to out-patients - if the GP suspects the cause may be malignancy then an urgent cancer referral should be made.
- Consider urgent referral for hospital admission if patient unwell, for example:
 - Severe jaundice
 - Severe ascites
 - Encephalopathy
 - Septic

(Patient UK 2006b)

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Lipid Levels

Rationale

Dyslipidaemia is a key component of the metabolic syndrome and a precursor for cardiovascular disease.

Recommended action

Fasting lipid profile should be assessed at:

- Initial visit/initiation of new medication (Barnett *et al.* 2007)
- 12 week follow-up visit (Barnett *et al.* 2007)
- Six monthly on a long-term basis (Barnett *et al.* 2007)
- Support and exchange information on diet (e.g. meal planning) and exercise.

Abnormal levels refer to GP (secondary prevention) (NICE 2008) who may:

- Offer simvastatin 40mg (or drug of similar efficacy and cost) to all adults with clinical evidence of CVD
- Consider increasing simvastatin dose to 80mg or drug of similar efficacy and cost if TC and LDL-C targets not reached
- Offer higher intensity statin (eg simvastatin 80mg) to people with acute coronary syndrome. Do not delay until lipid levels available; measure fasting lipid levels after approximately 3 months
- If potential drug interactions or simvastatin 40mg contraindicated, offer lower dose of simvastatin or pravastatin

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Glucose

Rationale

Diabetes occurs in 15% of people with schizophrenia (Holt and Peveler 2005), and only 5% of the general population (Busche and Holt 2004).

Risk factors include: family history of diabetes, physical inactivity, poor diet, smoking and the metabolic effects of antipsychotic medication (Gough and Peveler 2004). Typical antipsychotics, in particular the low potency ones such as chlorpromazine may induce or make existing diabetes worse (Newcomer *et al.* 2002). The atypical antipsychotics clozapine and olanzapine are associated with new onset or exacerbating type 2 diabetes, not just through their propensity to cause greater weight gain than other newer agents, but because of their effects on glucose regulation (Newcomer *et al.* 2002). There are also case reports linking risperidone and quetiapine to impaired glucose intolerance, diabetes and ketoacidosis (Taylor *et al.* 2007).

Recommended action

- All patients receiving antipsychotic therapy should be assessed for impaired glucose tolerance or diabetes at the start of treatment by having fasting blood glucose test (Barnett *et al.* 2007)
- Barnett *et al.* (2007) suggest checks should be made at the 12-week follow-up visit and every 6 months for patients with no change in initial values. Blood

- glucose should be checked at least annually. It may be more practical to do a random test though a fasting test will be more accurate
- More frequent assessments are required for patients with significant risk factors for diabetes (overweight, Asian/African ethnicity etc) (Barnett *et al.* 2007). Consider checking every 6 months
 - Support and exchange information on diet (ie meal planning) and exercise

Diabetes assessment

If FPG ≥ 7.0 mmol/L or random plasma glucose ≥ 11.1 mmol/L:

- Check for symptoms of diabetes (polyuria, nocturia, polydipsia, fatigue, visual disturbances)
- Test for urine ketones if symptoms are present (Barnett *et al.* 2007)
- Refer to GP for further investigations, education and treatment (usually provided by practice diabetes nurse)

Prolactin

Prolactin tests are included in the HIP as an action when breast self examination, menstruation and/or sexual satisfaction parameters flag red.

Rationale

Hyperprolactinaemia is a common side-effect of many antipsychotic drugs. Symptoms include gynaecomastia, galactorrhoea, amenorrhoea and sexual dysfunction. Switching to a prolactin sparing antipsychotic has been shown to lead to normalization of serum prolactin and resolution of the symptoms (Haddad *et al.* 2001).

Consensus guidelines for managing hyperprolactinaemia (Peveler *et al.* 2008) recommend that healthcare professionals should monitor proactively for hyperprolactinaemia as it may be asymptomatic.

Recommended action

- Patients prescribed prolactin elevating antipsychotics should, where possible, have this issue explained to them prior to commencing treatment and be screened for symptoms suggestive of hyperprolactinaemia before starting treatment (Haddad *et al.* 2001) and annually thereafter
- If the elevation of prolactin levels is mild (<1000 mIU/L (~ 50 ng/mL)) then it may be reasonable to continue to monitor the level. However, if even a mildly elevated level persists for more than 3 months, particularly if accompanied by amenorrhoea, bone mineral density may be compromised, and the possibility of reducing dose or switching to an antipsychotic with lower potential for prolactin elevation should be discussed with the patient

- When elevation is persistent and >1000 mIU/L (~50 ng/mL) then the clinician should consider switching to a drug with a lower potential to elevate prolactin if this can be achieved safely and is consistent with the clinical status of the patient as a whole
- For female patients switching to a drug with a lower potential to elevate prolactin may result in the return of fertility, and contraceptive advice should be given.
- If switching to a drug with a lower potential to elevate prolactin is not possible, it would be reasonable for clinicians to consider offering an oral contraceptive to female patients with amenorrhoea, if this is not contraindicated, to reduce the risk of subsequent osteoporosis.
- In any patient with a prolactin elevation greater than 3000 mIU/L (~150 ng/mL) then a prolactinoma should be considered.
- If the levels do not return to normal upon switching to a less prolactin-elevating antipsychotic, or if such switch is not possible for clinical reasons, then referral to a specialist in endocrinology is warranted to exclude a prolactinoma.
- Opticians may identify signs of optic chiasmal compression and advise an urgent referral to a specialist in endocrinology. If the patient has problems with their eyesight encourage them to see an optician and report this in your GP letter.
- The use of dopamine agonists to treat antipsychotic induced hyperprolactinaemia would only be considered in exceptional circumstances due to the serious risk of worsening the psychosis (Peveler, R. *et al.* 2008)

Other blood tests

These blood tests are not included in the HIP as specific risk factors in serious mental illness as they often form part of local protocols for physical examination on admission to services and/or care pathways and may be recommended when monitoring specific medications (e.g. Lithium). They are included here for information as they may be additionally ordered when any patient presents with symptoms or for additional investigations for a red flagged item.

Urea and Electrolytes (U & Es) and calcium

Rationale

For patients taking lithium, there is a higher than normal incidence of hypercalcaemia, and abnormal renal function (BMA 2008).

It will detect:

- Renal failure.
- Hyponatraemia in polydipsia, liver failure, diarrhoea and other diseases.
- Hypokalaemia in elderly patients with poor nutrition.

- Low urea in starvation and chronic liver disease.
- High urea in dehydration.

Recommended action

- Check U & Es and calcium annually or when presented with symptoms.
 - For patients taking lithium six monthly checks are recommended (BNF 2009).
-

Thyroid Function Test

Rationale

For patients taking lithium, there is a higher than normal incidence of hypothyroidism (BMA 2008).

Studies have indicated that the elevated serum levels of T4 may be specific for acutely ill schizophrenic patients and that neuroleptic medication may affect thyroid hormone metabolism (Baumgartner *et al.* 2000) and that there is a spectrum of thyroid function test abnormalities in chronic schizophrenia (Othman *et al.* 1994).

Recommended action

- Check thyroid function annually or in the presence of symptoms
 - For patients taking lithium, six monthly checks are recommended (BNF 2009).
-

Full Blood Count (FBC)

Rationale

A recent case-control study (Teixeira *et al.* 2009) in patients with schizophrenia showed a significantly higher number of patients with changes on leukocytes. Many patients presented low values of haemoglobin, erythrocytes and platelets. Leukopenia and neutropenia are recognised as side effects of antipsychotic medication (Taylor *et al.* 2007).

Recommended action

Check FBC annually or in the presence of symptoms.

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B12 and Folate

Rationale

A recent case-control study (Teixeira *et al.* 2009) in patients with schizophrenia presented low values of vitamin B12.

Having a deficiency of vitamin B12 just because of eating a poor diet is rare in Western countries, but unhealthy diets are common lifestyle choices of people with schizophrenia (McCreadie 2003).

Recommended action

Check B12 and folate annually or in the presence of symptoms.

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Plasma Levels

Lithium

Rationale

There is potential toxicity caused by lithium therapy when the serum levels are outside of the narrow therapeutic range (BMA 2008).

Recommended action

Due to risk of toxicity, it is recommended that lithium levels are monitored every three months to make sure they are within the therapeutic range (BNF 2009).

Carbamazepine

Rationale

Most authorities agree that plasma drug level monitoring is mandatory when using carbamazepine for seizure disorders and helpful for bipolar disorder (Taylor *et al.* 2000).

Recommended action

The carbamazepine levels should be monitored annually and be in therapeutic range.

Valproate

Rationale

Most authorities agree that plasma drug level monitoring is helpful for valproate in seizure disorders and bipolar disorder (Taylor *et al.* 2000).

Recommended action

The valproate levels should be monitored annually and be in therapeutic range.

Screening

Cervical Cytology (Women only)

Rationale

Cervical screening saves approximately 4,500 lives per year in England (Peto *et al.* 2004) and prevents up to 3,900 cases of cervical cancer per year in the UK (Sasieni *et al.* 1996). Cervical cancer incidence fell by 42 % between 1988 and 1997 (England and Wales). This fall is directly related to the cervical screening programme (National Statistics 2000).

Women with schizophrenia have a lower cervical cancer screening rate (63%) than those without severe mental health problems (73%) (Disability Rights Commission 2006). However, the evidence shows that if a woman has never been sexually active, then her risk of developing cervical cancer is very low indeed (NHS Cervical Screening Programme 2009a).

Recommended action

Determine patient history of cervical cytology.

If no recent cervical cytology and has been sexually active, then prompt/support to make appointment with the practice nurse in primary care.

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Prostate and Testicles check (Men only)

Rationale

Prostate cancer is now the most common cancer in men in the UK (not counting non melanoma skin cancer). More than 34,000 men are diagnosed each year – that's 24 out of every 100 cancers diagnosed in men. Prostate cancer is quite rare in men under 50. Prostate cancer is more common in Black Caribbean, Black African and mixed race men than it is in white or Asian men. In Britain, Indian and Pakistani men have a higher risk than white men, but Chinese and Bangladeshi men have a lower risk (Cancer Research UK 2002a).

Cancer of the testicles accounts for only about 1% of all cancers in men. It is however, the most common type of cancer in males ages 16 to 35, and can occur anytime after age 15. Often, only one testicle is affected. The cause of testicular cancer is still unknown, but risk factors include:

- Uncorrected undescended testicles in infants and young children
 - A family history of testicular cancer
 - Having an identical twin with testicular cancer
 - Injury to the scrotum or to a testicle
- (Cancer Research 2002b)

Recommended action

- Exchange information on testicular self-examination (Cancer Research UK 2002b). How to do a testicular self examination (leaflet): www.cancerhelp.org.uk/help/default.asp?page=3570
- Emphasise that further advice is freely available from local health promotion services
- The use of the PSA blood test as part of a screening programme is still under discussion in the UK and large international trials are being carried out to research whether prostate screening could be helpful (Cancer Research UK 2002a)

Urgent referral for possible cancer of the prostate are: abnormalities in the prostate felt during a rectal examination, a raised PSA test, a borderline PSA test followed by a repeat test one to three months later that shows the level is rising, and a raised PSA reading together with other symptoms that may be linked to prostate cancer (Cancer UK 2002a).

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Teeth

Rationale

Antipsychotics, antidepressants and mood stabilisers can cause reduced saliva flow (Robson and Gray 2007). This leads to caries, gingivitis and periodontal disease (Robson and Gray 2007).

Dental health may also be affected by poor diet and oral hygiene, and smoking (Robson and Gray 2007).

The extent of dental disease can be directly related to schizophrenia intensity, impact of negative symptoms and the length of hospitalisation (Thomas *et al.* 1996).

Recommended action

Dental check-ups should be every 12 months to two years. Patients should be encouraged to take regular visits to the community dentist (NICE 2004a). Provision of NHS dentistry can be limited in some areas of the UK and patients may need support to find and access one using the NHS choices website <http://www.nhs.uk>

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Eyes

Rationale

Antipsychotic medication may cause lens and cornea damage, and has been associated with cataract development (Robson and Gray 2007).

Recommended action

- Patients with severe mental illness should be encouraged to routinely visit a local optician/optometrist.
 - Prompt patients to self-refer, or refer, to an optometrist if no eye examination in the last two years.
 - Consideration should always be given to any sight aids (eg glasses, contact lenses) (Dougherty *et al.* 2004b).
-

Feet

Rationale

Some patients with severe mental illness struggle to maintain their personal care. Lack of proper care, ill-fitting shoes and general foot neglect are responsible for the majority of foot problems. Feet are the foundation of the body, so if the foot is not functioning correctly, ankles, knees, hips and lower back are not aligned correctly and problems can develop throughout the entire body.

Recommended action

- Exchange information on keeping feet healthy, eg washing daily, trimming nails, treatment for burns, cuts and breaks in the skin (The Society of Chiropodists and Podiatrists 2005)
 - Elderly patients or those with diabetes, osteoarthritis and/or rheumatoid arthritis should be a priority in NHS foot care, and should receive regular check-up from a registered chiropodist (The Society of Chiropodists and Podiatrists 2007)
 - If the patient is presenting any signs/symptoms of foot problems refer to the chiropodist.
-

Breast Examination (Women)

Rationale

Breast cancer is the most common cancer in the UK (Breast Cancer Care 2000). Hyperprolactinaemia can be an adverse effect of antipsychotic therapy that leads to breast-related problems (Halbreich *et al.* 2003).

Recommended action

- Patients aged between 50–70 years are eligible for a breast screening every three years (Breast Cancer Care 2000)
- Patients under 50 years are not invited for screening and should be advised on self examination (Breast Cancer Care 2000)
- Determine frequency of breast examinations (Breast Cancer Care 2000)
- Check risk factors for breast cancer (eg previous history, family history, age) (Patient UK 2007)

- Advise patient on any breast changes they should be aware of (Breast Cancer Care 2000)
- If there are any breast abnormalities, refer for further investigations (Patient UK 2007)
- Check for increased levels of serum prolactin (Halbreich *et al.* 2003)

Breast Examination (Men)

Rationale

The causes of breast cancer in men are not fully known. However, the most important risk factor is increasing age. Most men who get breast cancer are over 60 although younger men can be affected (Breast Cancer Care 2008).

Hyperprolactinaemia can be an adverse effect of antipsychotic therapy that leads to breast-related problems (Halbreich *et al.* 2003).

Recommended action

- Check risk factors for breast cancer (age > 60 years, previous radiotherapy to the chest, obesity, family history of breast cancer, high oestrogen levels, chromosomal syndromes) (Breast Cancer Care 2008)
- Check for any symptoms (painless lump, nipple discharge, ulceration or swelling) (Breast Cancer Care 2008)
- Refer to primary care for further investigations if symptoms are reported or observed (Breast Cancer Care 2008)
- Check for increased levels of serum prolactin (Halbreich *et al.* 2003)

Menstrual Cycle

Rationale

Hyperprolactinaemia can cause amenorrhoea (GP Notebook 2009). Amenorrhoea is associated with anovulation (absence of ovulation), and infertility (GP Notebook 2009).

Recommended action

- Check for amenorrhoea - consider offering an oral contraceptive, if this is not contraindicated, to reduce the risk of subsequent osteoporosis
- Check for increased levels of serum prolactin = anovulation, disturbed menstrual cycle and irregular menstrual cycle (Halbreich *et al.* 2003). See under Blood Tests – prolactin

Lifestyle

Sleep

Rationale

Most adults need around 7–8 hours of sleep each night (Benson 2006).

- In untreated schizophrenia, profound insomnia can result from psychotic symptoms (Benson 2006)
- Although antipsychotic treatment can reduce insomnia, the side effects of sedation and residual insomnia can occur (Benson 2006)
- Complaints of poor sleep quality are directly related to negative assessments of quality of life (Benson 2006)
- Improved sleep may lead to improved ability to cope with stress, and increased energy (Hofstetter *et al.* 2005)

Recommended action

- Clarify any patient sleep problems (Hofstetter *et al.* 2005)
 - Provide education on good sleep hygiene and benefits of a sleep diary (Gray *et al.* 2005)
 - Consider medication review – refer to ‘Risk and Relapse Plan’ if relapse suspected (Gray *et al.* 2005)
-

Smoking

Rationale

Approximately 85% of people with schizophrenia smoke, compared with 23% of the general population (Goff *et al.* 2005). Smoking rates are higher in schizophrenia than in other severe mental illnesses (Goff *et al.* 2005).

Neurobiological, psychological, behavioural and social factors make it difficult for patients with mental illness to stop smoking (Robson and Gray 2007).

Smoking cessation medication and other non-pharmacological support can increase abstinence rates in those with mental health problems to as high as those in the general population (Foulds *et al.* 2006, Campion *et al.* 2008). However those with mental illness have previously been less likely to receive smoking cessation in primary care (Phelan *et al.* 2001).

Stopping smoking reduces the risk of (NHS Choices 2009a):

- Developing illness, disability or death caused by cancer, heart or lung disease
- Gangrene or amputation caused by circulatory problems
- Exposing others to secondhand smoke
- Children in the same household suffering from asthma or glue ear
- Infertility levels, and an unhealthy pregnancy and baby

- Breathing difficulties and decreased general fitness
- Less enjoyment of the taste of food

Recommended action

- Give advice about the possible health risks associated with smoking
- Ask about respiratory symptoms; refer for chest examination if appropriate
- Refer any patients wishing to quit smoking to NHS Stop Smoking Services if appropriate (DH 2007a) or their local GP practice stop smoking service. Review medication regularly.
- Cigarette smoking lowers the levels of many antipsychotic medications (Vazquez *et al.* 2007). Therefore, if a patient stops or reduces their smoking or starts smoking again after a period of abstinence, a medication review should be undertaken.
 - Blood levels of olanzapine and clozapine should be measured before smoking cessation followed by 25% dose reduction during first week of cessation and then further blood levels (Taylor *et al.* 2007).
 - Doses of fluphenazine and benzodiazepine should be reduced by up to 25% in first week of cessation.
 - Tricyclic antidepressants may need to be reduced by 10-25% in first week (Taylor *et al.* 2007).

Nicotine replacement is available in a variety of forms and strengths to encourage patient preference and acceptability. Combining patch and faster-acting oral NRT improves efficacy. Side effects include mild local irritation of mouth, throat or nose (FPH 2009).

Bupropion is associated with seizures and is contraindicated in bipolar affective disorder and epilepsy. It should not be prescribed with drugs which increase risk of seizures such as tricyclic antidepressants and some anti-psychotics. Bupropion can also alter blood levels of medication such as antipsychotics and antidepressants (FPH 2009).

Varenicline has been reported to be more effective and have fewer side effects than bupropion (Cahill *et al.* 2007). However, reports of exacerbation of depression and suicidal ideation are currently being reviewed (FPH 2009).

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Exercise

Rationale

Physical inactivity is a leading cause of death in developed countries (WHO 2003).

People with severe mental illness are more physically inactive than the general population (Brown *et al*, 1999, McCreddie 2003).

Physical activity can have a positive effect on psychological well-being in people with schizophrenia (DH 2004).

Recommended action

Identify the patient's level of activity. For those that are inactive recommend 30 minutes of activity five days a week (DH 2004).

These individuals should be followed up at appropriate intervals over a three to six month period (DH 2004).

Refer onto an exercise referral scheme if required (DH 2004). Check what the local council has on offer.

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Alcohol Intake

Rationale

There is considerable evidence to support the positive impact of reducing unsafe alcohol consumption on cardiovascular health (NHS Information Centre 2008).

Many of the antipsychotics can impair alertness and concentration. Antipsychotics can cause sedation and impair coordination. The use of alcohol can further increase any impairment (Rethink 2008b).

Recommended action

Offer recommendations on sensible daily alcohol intake:

- Adult women should not regularly drink > 2–3 units of alcohol a day
- Adult men should not regularly drink > 3–4 units of alcohol a day
- Women who regularly drink > 6 units a day (or > 35 units a week) and men who regularly drink > 8 units a day (or 50 units a week) are at highest risk of alcohol-related harm

(Department of Health 2007b)

Refer to local Alcohol Support Agency.

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Diet

Rationale

In a survey of the dietary habits of 102 people with SMI by McCreadie (2003) the average fruit and vegetable intake for these people was 16 portions a week, compared with recommended intake of 35 per week (DH 2004). The physical health consequences of a poor diet include CVD, diabetes, obesity and some cancers.

Studies of people with SMI repeatedly show that saturated fats from dietary intake of meat and dairy products are associated with worse outcomes in schizophrenia (Peet 2004). There is a particularly strong association between sugar consumption and poorer outcome in schizophrenia whereas consumption of fish and sea food, particularly omega 3 fatty acids, has been associated with better outcomes (Peet 2004).

Recommended action

- Explain that five portions of fruit/vegetables each day and reducing fat intake, reduces the risk of cancer, coronary heart disease, and other chronic illnesses (DH 2007c).
 - Aim to address potential barriers (access and availability of fresh fruit/vegetables, awareness of health benefits and attitudes towards buying, preparing and eating fruit/vegetables) (DH 2007c).
 - Agree and implement a diet plan with the patient (and any carers) – may include referral to other members of the multidisciplinary team (e.g. Occupational Therapist).
-

Fluid Intake

Rationale

Water makes up about two-thirds of the body's weight (FSA). It is essential for lubricating the joints and eyes, aiding digestion, flushing out waste and toxins and keeping skin healthy (NHS Choices 2009b). Dehydration occurs when the normal water content of your body is reduced, upsetting the delicate balance of minerals (salts and sugar) in the body fluid. Many of the body's cells depend on these minerals being maintained at the correct levels to function properly (NHS Choices 2009b).

Some of the early warning signs that someone is dehydrated are: feeling thirsty and light-headed, and having concentrated, strong-smelling urine. The body works less efficiently, even with a relatively low level of fluid loss (NHS Choices 2009b). Total water intake includes drinking water, water in beverages (non-caffeinated and non-alcoholic) and water in food (FSA).

Overconsumption of fluid can also arise from a condition called polydipsia which is a serious complication of some psychotic illnesses, including schizophrenia. The exact

reason for any one person developing polydipsia is unclear, but if untreated, the high intake of fluids can lead to hyponatraemia, which in turn can lead to coma or even death. It has been estimated that between six and 17% of psychiatric inpatients suffer from polydipsia (Brooks and Ahmed 2007).

Recommended action

Determine patient's daily fluid intake

If < one litre/day:

- Check for signs of dehydration (FSA)
- Encourage the patient to drink 1-2 litres (6–8 glasses) of fluid every day (more during hot weather and physical exertion) (FSA)
- Exchange information on increasing fluid intake (drinking semi-skimmed milk, diluted fruit juices, diluted fruit squash) (FSA)

If > three litres/day check for signs of polydipsia, (Brooks and Ahmed 2007) such as increased urine output.

Implement a fluid balance chart if possible; enlist help of carers and family.

Electrolyte assessment if initial intervention is unsuccessful.

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Urine

Rationale

Polyuria = the passing of excessive volumes of urine may be a sign of diabetes, renal failure, alcohol and drug misuse, metabolic abnormalities (Patient UK 2005) and polydipsia.

Oliguria = reduced urine volume. Cause maybe due to dehydration, vascular collapse or low cardiac output (Patient. UK 2008).

Dehydration = $\geq 1\%$ reduction in total body weight due to fluid loss. The body works less efficiently, even with a relatively low level of fluid loss (NHS Choices 2009b). Many medical conditions can be detected by using medical urine test strips.

Recommended action

- Assess for signs of dehydration (NHS Direct 2007), encourage fluids and implement fluid balance chart to evaluate
- Assess for symptoms of polyuria (Patient. UK 2005), implement fluid balance chart to evaluate
- Check for any urine frequency/incontinence issues
- Dip test urine using multistix diagnostic strips. Follow usual protocols for abnormalities

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Bowels

Rationale

People with schizophrenia are almost twice as likely to have bowel cancer as the general population (DRC 2006).

Patients with schizophrenia seldom complain of gastrointestinal symptoms unless specifically asked (Gupta *et al.* 1997).

Eating a diet low in red or processed meat and high in fibre, fruit and vegetables can reduce the risk of bowel cancer. Being physically active helps to cut the risk, but being overweight or regularly drinking too much alcohol increases it (Cancer Research UK 2009).

Recommended action

- Exchange information on increasing physical activity, lowering alcohol and a healthy diet
 - The NHS Bowel Cancer Screening Programme offers screening every two years to all men and women aged 60 to 69 (NHS Cancer Screening Programmes 2009b)
 - Check for signs of irritable bowel symptoms, diarrhoea or constipation, excessive urgency, gastrointestinal symptoms, straining, bleeding, need for laxatives
 - Check for any bowel frequency/incontinence issues
 - Refer to GP who can make a rapid referral for endoscopy if symptoms are suspicious (NICE 2004b)
-

Caffeine intake

Rationale

Caffeine is a central stimulant, e.g. it stimulates the brain. Caffeine is present in drinks such as coffee, tea and cola (NWMHP 2008). Too much caffeine can cause feelings of anxiety and nervousness, sleep disruption (especially difficulty getting off to sleep), restlessness, irritability, diuresis (passing lots of water/urine), stomach complaints, tremulousness, palpitations and arrhythmias (changed heart rate, especially faster beating) (NWMHP 2008). A moderate daily caffeine intake of 250–500 mg is not associated with adverse events (NWMHP 2008).

Psychosis can be induced in normal individuals ingesting caffeine at toxic doses, and psychotic symptoms can also be worsened in schizophrenic patients using caffeine (Broderick and Benjamin 2004).

Caffeine content

	Average caffeine content
1 cup of coffee	75–100 mg
1 cup of tea	50 mg
1 can of cola	40 mg
1 energy drink	90 mg
Bar of plain chocolate	50 mg
Bar of milk chocolate	25 mg

(FSA 2004)

Recommended action

- Exchange information on reducing caffeine intake (stopping gradually to avoid withdrawal effects) (NWMHP 2008)
 - Check for symptoms of caffeinism or caffeine toxicity (> 1000 mg/day), which can make illnesses such as anxiety more resistant to drug treatment (NWMHP 2008)
-

Safe Sex

Rationale

Although a smaller proportion of people with SMI are sexually active compared to the general population, those that are sexually active are more likely to engage in high risk behaviours that may lead to HIV, such as sex without a condom and injecting drug use (Cournos et al. 2005). Reasons for this include lack of knowledge about how sexually transmitted diseases (STIs) and HIV are transmitted and prevented (Arrufo et al. 1990, Kalichman et al. 1994), a susceptibility to coercion into unwanted sexual activity, difficulties in establishing stable social and sexual relationships, and comorbid alcohol and substance use (Coverdale and Turbott 2000).

Recommended action

- Identify if the patient is engaging in behaviours that increase the risk of STIs
 - Provide sexual health advice
 - If STI is suspected, refer to the Genito-Urinary Medicine Clinic
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Sexual Satisfaction

Rationale

Antipsychotic medication can have an adverse effect on sexual function, which impacts greatly on quality of life (Hanssens *et al.* 2006).

A study (Smith *et al.* 2002) showed that sexual dysfunction occurred in 45% of patients taking antipsychotic medication. The main cause of sexual dysfunction in both men and women was hyperprolactinaemia.

Recommended action

- Determine the patient's level of sexual activity – refer for gynaecological examination and laboratory assessments if required (EAU 2005)
 - Use side effects scale for antipsychotic medication such as SESCAM (Bennett *et al.* 1994)
 - Perform systemic assessment (eg Arizona Sexual Experience Scale- go to: www.psy-world.com/asex_print.htm) (McGahuey *et al.* 2000)
 - Check for increased levels of serum prolactin = decreased libido and arousal, orgasmic dysfunction (Halbreich *et al.* 2003)
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Cannabis

Rationale

Cannabis use is associated with poor outcome in existing schizophrenia and may precipitate psychosis in individuals with pre-existing liability (Henquet *et al.* 2005). Cannabis use is a contributing factor in 10% of schizophrenia cases (BBC 2007). There are 1,500 expected new cases of cannabis-related schizophrenia each year (BBC 2007).

Recommended action

- Patients' cannabis use should be recorded during a physical health check
 - Ask about other non-prescribed drug use (BMA 2008)
 - Implement health behaviour interventions and evaluate systematically using a drug-use scale
 - Consider working with support of dual diagnosis worker/service to enhance interventions and evaluation/access clinical supervision.
-

Medication review

People with an established diagnosis of schizophrenia, schizoaffective disorder or bipolar disorder who are managed in primary or secondary care require monitoring of medication use, medication adherence and side-effects (NICE 2006a; 2009).

Antipsychotics

Rationale

Antipsychotics have a wide range of side effects. The most widely researched include (Rethink 2006):

Sedation: The antipsychotics that cause the most sedation include chlorpromazine, promazine, thioridazine, clozapine and zotepine. Often this can be dealt with by the patient taking their medication at night just before they go to bed. The dose may need to be reduced or changed if this is a big problem.

Movement disorders: There are different types of movement disorder. These include:

- **Dystonia** - prolonged muscle spasms often involving the face, neck, shoulders and upper limbs. Drugs such as procyclidine and orphenadrine are given to treat dystonia
- **Akathisia** - fidgety movements of the legs which may be accompanied by a strong sense of inner restlessness and unease. This often means that a person cannot sit comfortably, and may be driven to walk up and down to try and gain relief. It is best treated with clonazepam or propranolol
- **Parkinsonian movement disorders** - involve stiffness and shakiness, and resembles the unrelated condition of Parkinson's disease. The limbs move slowly and muscles of the face may be quite immobile, producing an expressionless, staring face. Rhythmic shaking may occur but is not usually very severe, and is most obvious in the hands. Procyclidine and orphenadrine, amongst other drugs, are given to treat Parkinsonian movement disorders
- **Tardive dyskinesia** - major signs of the condition are excessive movement of the lips, tongue and jaw, (known as oro-facial dyskinesia). The term "tardive" means delayed or late-appearing and this reflects the fact that treatment may have gone on for some months or years before the movement disorder becomes apparent. Oro-facial dyskinesia is the most common form of tardive dyskinesia. Other abnormal movements are seen including jerky, abrupt movements of the limbs and body, but these are less common.

Recommended action

Side effects should be monitored in a systematic manner using a recognized tool such as SESCOAM (Bennett *et al.* 1995). This is a two part scale, one for the observing health care professional and the other is self rated by the patient.

Blood tests should be taken as described above.

Refer back to original prescriber (NICE 2009) in the case of:

- Observed side effects
- Return of symptoms
- Any physical problems which may be related to the drug
- Any issues flagged up by the patient

Mood stabilisers

Contraceptive status should be checked in all women of child-bearing age prescribed mood stabilisers due to teratogenic risks (Taylor et al, 2009).

Lithium

Rationale

In long-term use lithium has been associated with thyroid disorders and mild cognitive and memory impairment. Lithium salts have a narrow therapeutic/toxic ratio, therefore it is important to determine the optimum range for each individual patient. Lithium toxicity is made worse by sodium depletion (BNF 2009).

Recommended action

- Check thyroid function, U & Es, and calcium six monthly (BNF 2009))
- Check lithium levels three monthly (BNF 2009). Refer back to prescriber if not in therapeutic range
- Patients should be maintained on lithium after three to five years only if benefit persists (BNF 2009)

Carbamazepine

Rationale

In order to be effective, carbamazepine has to reach a given level in the blood (NWMHFT 2005a). Side effects include dizziness, drowsiness, shaky movements and feeling sick. Carbamazepine can cause a chronic low white blood cell count which increases susceptibility to infection (NWMHFT 2005a). This can be monitored with regular blood tests.

Recommended action

- The carbamazepine levels should be monitored annually and be in therapeutic range
- Check full blood count annually
- Refer back to prescriber if not in therapeutic range

Valproate

Rationale

Valproate causes an increase in appetite and therefore weight gain (NWMHFT 2005b). Side effects include dizziness, drowsiness, shaky movements and feeling sick, impaired liver function, thrombocytopenia and impaired platelet function (NWMHFT 2005b).

Recommended action

- Give advice regarding a diet high in vegetables and fibre, refer to dietician if appropriate (NWMHFT 2005b)
 - Advise if bruises without reason or bleeds easily, to stop taking valproate and see their doctor (NWMHFT 2005b)
 - The valproate levels should be monitored annually and be in therapeutic range
 - Check full blood count and LFT annually
 - Refer back to prescriber if not in therapeutic range
-

Additional information about annual health checks in primary care

The GMS contract stipulates that the practice has a register of people with schizophrenia, bipolar disorder and other psychoses and that regular physical health checks are part of the mental health review, alongside regular review of medication (BMA, 2008). However no detail is given about the parameters to check so interpretation and delivery by individual practices can be extremely variable.

Care plan

Rationale

The GMS contract (BMA 2008) requires the patient to have their care plan documented in the primary care records; this is agreed between individuals, their family and/or carers as appropriate

Recommended action

- If the patient is under the care of secondary care, Care Programme Approach (CPA), the care plan is scanned into the patient record
- If the patient is on the practice SMI register but **not** under the care of secondary care, the healthcare professional should document an accurate and easily understood plan of care as part of the annual review by discussing this with the patient, family and/or carers. The discussion should include the patient's preferred course of action in the event of a clinical relapse; it should also contain a discussion around the following issues (NICE 2009):
 - Social support
 - Input from secondary and /or voluntary mental health
 - Early warning signs that may indicate possible relapse
 - Occupational status

Flu vaccination

Rationale

Patients with severe mental illness are at an increased risk of cardiac, respiratory disorders and diabetes (Sainsbury Centre for Mental Health 2003).

Recommended action

Offer annual immunisation (Sainsbury Centre for Mental Health 2003).

Follow up

Rationale

The patient may not attend for the annual health check in primary care due to his/her mental state. It is important, therefore to set up a robust system to allow further opportunities to attend. It is a requirement of the GMS Contract (BMA 2008) that if

the patient does not attend the annual review, this is followed up by the practice team within 14 days of non-attendance

Recommended action

- Send a letter requesting that they contact the surgery to make a new appointment
 - If unknown to secondary care, inform the GP of their non-attendance
 - If known to secondary care, inform the secondary care link worker
 - If patient does not make a further appointment they can then be exception reported
-

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How to contact the HIP Research Team

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Appendix 3
Letter from REC



National Research Ethics Service
Cambridgeshire 4 Research Ethics Committee

Victoria House
Capital Park
Fulbourn
Cambridge
CB21 5XB

Telephone: 01223 597685
Facsimile: 01223 597645

01 December 2010

Professor Richard John Gray
Professor of Research Related to Nursing and Director of Postgraduate Research &
Honorary Nurse Consultant
University of East Anglia
Faculty of Health
University of East Anglia
Edith Cavell Building, Norwich
NR4 7TJ

Dear Professor Gray

Study Title: Cluster randomised controlled trial of the Serious Mental
Illness Health Improvement Profile (HIP)
REC reference number: 10/H0305/73

Thank you for your letter of 19 November 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Questionnaire: Appendix 12.1 SF36v2		
Questionnaire: Appendix 13.2 Health Resource Use (nurse)	1	05 October 2010
Participant Information Sheet: Appendix 5.2 - Nurse Information Part 2	3	15 November 2010
Response to Request for Further Information	Richard Gray	19 November 2010
Participant Consent Form: Appendix 8.3 Patient part 1	2	04 October 2010
Participant Consent Form: Appendix 8.4 patient part 2	2	04 October 2010
Questionnaire: Appendix 12.1 EQ5D		
Questionnaire: Appendix 12.3 PHASe (adapted with MCQ's)		
Questionnaire: Appendix 12.4 QRISK@2		
Questionnaire: Appendix 13.1 Health Resource Use (Patient)	1	05 October 2010
Questionnaire: Appendix 13.3 HIP Audit form	2	30 September 2010
REC application	50756/15633 0/1/833	07 October 2010
Participant Consent Form: Appendix 8.5 psychiatrist/GP part 2	2	04 October 2010
Participant Information Sheet: Appendix 5.1 - Nurse Information Part 1	3	15 November 2010
Appendix 16.2 Statistician CV	1	01 September 2010
Appendix 14.1 HIP Male and Female	2	31 August 2010
Appendix 11.3 psychiatrist/GP part 2 interview schedule	2	05 October 2010
Appendix 10.5 CI response to Peer Review by RfPB panel		07 December 2009
Letter from funder - Appendix 9.1 NIHR RfPB competition 9 award letter		23 November 2009
GP letter Appendix 7.1 part 1	1	04 October 2010
Letter of invite to participants - Appendix 6.1 Nurse part 1	2	04 October 2010
CV for Richard Gray		27 September 2010
Letter of invite to participants - Appendix 6.5 Psychiatrist/GP Part 2	2	04 October 2010
Appendix 10.4 NIHR RfPB Peer Review 4		23 November 2009
Appendix 16.1 Acting Director of Nursing NWMHFT CV	1	05 October 2010
Protocol	Appendix 2, version 10	30 September 2010
Participant Consent Form: Appendix 8.1 Nurse part 1	2	04 October 2010
Participant Consent Form: Appendix 8.2 Nurse part 2	2	04 October 2010
Participant Information Sheet: Appendix 5.5 - Psychiatrist/GP	3	15 November 2010

Information Part 2		
Participant Information Sheet: Appendix 5.4 - Patient Information Part 2	3	15 November 2010
Participant Information Sheet: Appendix 5.3 - Patient Information Part 1	3	15 November 2010
CV for Jacqueline White		27 September 2010
Letter of invite to participants - Appendix 6.2 Nurse part 2	2	04 October 2010
GP letter Appendix 7.2 part 2	1	04 October 2010
Appendix 10.1 NIHR RfPB Peer Review 1		23 November 2009
Appendix 10.6 NIHR RfPB Final acceptance		05 February 2010
Letter of invite to participants - Appendix 6.3 Patient part 1	2	04 October 2010
Appendix 10.2 NIHR RfPB Peer Review 2		23 November 2009
Appendix 11.1 Nurse part 2 focus group schedule	2	05 October 2010
Appendix 15.1 CI research passport		20 October 2010
Letter of invite to participants - Appendix 6.4 Patient part 2	2	04 October 2010
Appendix 10.3 NIHR RfPB Peer Review 3		23 November 2009
Appendix 11.2 patient part 2 interview schedule	2	05 October 2010
Appendix 15.2 Trial Coordinator NWMHFT Hon Contract	1	01 October 2010
Appendix 16.4 Process Observation Lead CV	1	03 October 2010
Appendix 17 Shuel et al 2010 IJNS HIP evaluation	1	01 February 2010
Appendix 16.3 Health Economist CV	1	15 January 2010
Appendix 14.2 HIP manual	2	30 September 2010
Summary/Synopsis	10	30 September 2010
Covering Letter	Professor Richard Gray	07 October 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H0305/73

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

pp Nstorey

Dr Leslie Gelling
Chair

Email: Nicky.Storey@eoe.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mrs Brenda Jones
Norfolk and Waverney Mental Health NHS Foundation Trust
Research Office
Hellesdon Hospital
Drayton High Road
Norwich
NR6 5BE

Appendix 4

Participant Information and Consent Forms

**Cluster Randomised Controlled Trial of the Serious Mental Illness
Health Improvement Profile (HIP)**

Centre Number:

Study Number:

Principal Investigator:

Professor Richard Gray, Professor in Research Related to Nursing & Director of Postgraduate Research, University of East Anglia. Honorary Nurse Consultant, Norfolk and Waveney Mental Health NHS Foundation Trust

Trial Coordinator:

Jacquie White, Faculty of Health, Edith Cavell Building, University of East Anglia, Norwich NR4 7TJ

Organisations involved:

University of East Anglia
Norfolk and Waveney Mental Health Foundation NHS Trust
Lincolnshire Partnership NHS Foundation Trust

PART 1

What is the purpose of the study?

Physical health problems in people with serious mental illness are common and sometimes get overlooked. It is important to find out about these problems, as many can be treated, avoiding extra stress and helping recovery. We think mental health nurses are well placed to help patients recognise and address physical health problems, for example, by helping them consider changes to their diet, smoking and amount of exercise taken. However nurses working in mental health care often lack knowledge about physical health and confidence in this role to do this work effectively.

We have developed the Health Improvement Profile (HIP) to help mental health nurses work with patients to identify physical health problems and select the appropriate next steps to take. We have also developed a workshop to teach nurses how to use and implement the HIP.

The purpose of this study is to find out if mental health nurses and patients can find out about physical health problems and plan care together using the HIP. We will also calculate the costs of introducing the HIP and evaluate the experience of patients, nurses, psychiatrists, GPs and Primary Healthcare Teams where the HIP has been used. This research is being carried out as part of a PhD qualification supervised by Professor Richard Gray at the University of East Anglia.

Why have I been invited?

You have been invited to take part because you are a mental health nurse working in a Community Mental Health Service in Lincolnshire Partnership Foundation NHS Trust.. Across LPFT and Norfolk and Waveney Mental Health Foundation NHS Trust we are aiming to find at least fifty Community Mental Health Nurses and two hundred and fifty patients who are willing to take part.

Do I have to take part?

When you have read the invitation letter and had time to consider this information pack, it is up to you to decide. You do not have to send us the response slip, but it would be helpful if you did (even if you do not wish to take part in the study).

If you are interested in taking part, the Study Coordinator or a researcher will describe the study and review this information with you. If you would still like to take part she/he will then ask you to sign a consent form to show you have agreed to take part. If you change your mind at any time, you are free to stop taking part in the study, without giving a reason.

What will happen to me if I take part?

If you agree to take part, and after you have signed the consent form, we will ask you to complete a form to provide the research team with some general details about you and your qualifications. This is so we can make sure the nurses we identify for the study, reflect mental health nurses working in community teams across the UK.

You will then be randomly allocated to either enter the HIP Programme arm of the study or the 'Care as Usual Group' arm of the study. Computer software will be used to make sure you have an equal chance of being allocated to either group.

A researcher from the research team at UEA will then liaise with your Team Leader to screen patients on your caseload, to see if they are suitable to take part in the study. Suitable patients on your caseload will be randomly selected from this list of eligible patients and invited to take part in the study by letter, which we would ask you to pass on to them. We aim to recruit and consent 5 patients from the caseload of every nurse in the study.

We will then make an appointment for our Research Assistant to interview the patient to collect baseline data. This meeting will take 30 minutes and will take place in the Trust in a private interview room or in the patient's home if appropriate. In this meeting we will ask the patient about:

1. Services they currently receive as part of their health and social care;
2. Their views about how their physical health impacts on their life.

We may need to contact you directly after the interview to ask for clarification about the services received questions. After this meeting we will not interview the patient again for a whole year.

Once baseline patient interviews are completed, those nurses who were randomised into the HIP Programme Group will be invited to one of three possible dates for the HIP training workshop. The training will take six hours.

If you are in the HIP Programme Group, every time you use a HIP in practice with one of your consented patients over the next year we will ask you to send copies of the HIP form and a HIP use resource form to the research team. The resource form is to capture details of the time it takes to complete a HIP and the nature of any onward referrals made.

We will also ask you to keep us informed about any patient whose circumstances change significantly (e.g. Mental Health Act status) or who withdraws from the study for any reason over the course of the year by returning a form to us. If a patient loses capacity to consent to continue in the study they will be withdrawn from the study by the research team and we will inform them and you we are doing this.

At the end of a year, we will check with the original consented patients that they still want to continue in the study. For those who are still happy to take part, we will make an appointment for one of the researchers to interview the patients again. This meeting will take 30 minutes in a private interview room, or in the patient's home as before. In this meeting we will repeat the questions about:

1. Services they currently receive as part of their health and social care;
2. Their views about how their physical health impacts on their life.

We may need to contact you directly after the interview to ask for clarification about the services received questions.

After they have completed the first part of the study the Study Coordinator will audit the secondary (mental health) care patient record of 36 patients in the HIP Programme group for any evidence of the process of physical health care received by them over the last 12 months.

Research Method

We don't know the best way of identifying and planning physical health care. To find out, we need to compare different approaches and to do this researchers put people into groups and give each group a different approach. The results are then compared to see if one approach is better than the other. To try to make sure the groups are the same to start with, each person is put into a group by chance (randomly selected).

The HIP research study is called a 'cluster randomised controlled trial'. The nurses who agree to take part in this study are randomly assigned to either receive the HIP training, or carry on providing 'Treatment as Usual'. Half of all the nurses in the study will receive the HIP training, half of them will not. Computer software will be used to make sure each nurse has an equal chance of being allocated to the HIP or 'Treatment as Usual' group. The word 'cluster' is used because it is the nurses and not the patients who are put into groups. The outcome of this is that only the patients of half of the nurses in the study will experience their nurse using the HIP form over the course of the study year.

The audit of the patient record in the smaller sample of 36 patients in the HIP Programme group will provide more information about the process of using the HIP in practice.

Expenses and payments

We will provide transport and drinks in meetings. If additional expenses are incurred (e.g. the patient prefers to use public transport) we will reimburse these.

What will I have to do?

If you are randomised to receive HIP training, we will expect you to attend one of the 6 hour workshops and attempt to introduce the HIP tool into your practice. You will also be expected to complete and return the study forms provided to you at the beginning of the study and keep the research team informed throughout the study about any changes to the status of your consented patients (e.g. discharge, withdrawal of consent) or other changes which may impact on the study (e.g. a change in your role).

What is the procedure that is being tested?

The Health Improvement Profile [HIP] is being tested.

This tool was developed in the UK by a team of three mental health nurses following a review of the physical health problems experienced by people with serious mental illness. Early 'pilot' studies with small numbers of nurses and patients refined the tool (e.g. it was decided it was easier to use if it was made to fit on one side of paper).

A training workshop was then developed to train nurses to use the tool in their practice.

One of the first mental health nurses to be trained introduced the HIP into an outpatient clinic in Scotland and completed it with 31 patients. This demonstrated it could successfully identify physical health problems.

The patients, nurses and doctors in Scotland told us they liked the tool and said it helped them plan care together. To be really certain that the HIP has a positive impact on the physical health outcomes of patients, we need to measure the outcomes in much larger numbers of nurses and patients in a randomised controlled trial.

What are the alternatives for physical health training and practice?

The alternative is to use your usual supervision process with your line manager to identify your training needs and access continuing professional development education.

What are the possible disadvantages and risks of taking part?

You may be inconvenienced by the extra time required to collect information and complete and return study forms to the research team. If you are randomized to the HIP Training Group, you will also need to attend the 6 hour workshop.

Use of the HIP may lead to identification of physical health problems, you were not previously aware of in your patients and this may require more time with patients in visits to complete the assessment and plan care with them.

The next steps recommended in the HIP may include supporting your patients to attend extra appointments (e.g. with other health professionals) and/or arranging further investigations (e.g. blood tests).

The study is sponsored by Norfolk and Waveney Mental Health NHS Foundation Trust. If you are concerned about an increase in workload you should discuss this in the usual way with your line manager.

What are the possible benefits of taking part?

We cannot promise the study will help you, but the information we get from this study will help improve our knowledge of the treatment of users of mental health services. You may find taking part in the study leads to an increase in your knowledge, skills and confidence in the assessment and intervention to meet the physical health needs of your patients.

If the study is successful, you will have participated in a project, which will have a positive impact on the lives of many other patients.

What happens when the research study stops?

At the end of the study you will continue to practice as usual.

Norfolk and Waveney Mental Health NHS Foundation Trust has agreed to continue to support the clinical use of the HIP in practice, if the trial is successful.

If you did not receive the HIP training during the study and it has been found to be useful, you will be invited to a training workshop, so you can also learn to use the tool.

We are also interested to know more about how the use of the HIP may impact on care and the views of patients, nurses and doctors where the HIP has been used.

We may invite you and some of your patients to take part in this part of the study, after a year, if you are in the HIP trained group. We will ask you separately about this additional part of the study nearer the time and provide a separate information sheet and consent form should you be interested.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part I.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What if relevant new information becomes available?

Sometimes, when we are doing research, we get new information about the approach being studied. If this happens, the Study Coordinator will tell you and discuss whether you should continue in the study. If you decide to continue in the study, they may ask you to sign an updated consent form. If the study is stopped for any reason, we will tell you why.

What will happen if I don't want to carry on with the study?

If you wish to stop taking part, for any reason at all, please let the research team know (contact number) and they will withdraw you from the study.

If you decide to stop taking part after some anonymous information has already been collected from you, this data will still be analysed with the other participants' information. However, no more information will be added about you after you have been withdrawn.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team, who will do their best to answer your questions (contact number). If you remain unhappy and wish to complain formally, you can do this through your line manager and/or the Research and Development Team in Norfolk and Waveney Mental Health NHS Foundation Trust 01603 421340.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the Trust, but you may have to pay your legal costs.

The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What if a member of the research team believes they have observed poor practice or has concerns about possible poor practice reported to them?

Any poor practice concerns about participants or any other member of the care team will be reported to the appropriate line manager and followed up in writing within 24 hours.

Will my taking part in this study be kept confidential?

All information collected for this part of the study will be recorded on forms, which are given a unique study number. They will not include your name or work address. This is to make sure that information collected for the study does not individually identify you, your patients, other nurses taking part or doctors. All members of the HIP research team at the University of East Anglia will have access to the anonymised data.

The Consent Forms are the only forms which identify the patients and nurses in the study by name. These will be kept in a locked filing cabinet, within a locked office at the research team base at the University of East Anglia, alongside details of the unique study code numbers. Only the Principle Investigator and the Study Coordinator will be able to access this cabinet. This is in case there is a problem and we need to break the study code to enable us to contact you or your patients, their psychiatrists, GPs or care coordinators. If this happens we will tell you.

All the information collected during the trial will be archived at the end of the trial and kept in a secure room for 5 years. After 5 years it will be destroyed securely. NHS Research Governance staff may inspect all information collected and stored during the study, at any time, to make sure the research process has been carried out correctly. All staff participating in inspections are required to maintain the highest standards of confidentiality at all times.

Involvement of your line manager

We will inform your line manager after you consent to take part that you are participating in the HIP study.

What will happen to the results of the research study?

As soon as we have the results, we will send out a newsletter to share our findings with everyone who took part.

We started recruitment for the HIP study in **March 2010** and we plan to complete all the study work and be ready to report the results after three years.

Reports and presentations will be written by the research team to enable the results to be shared as widely as possible. These publications and presentations will not identify any nurse, patient or team by name.

Who is organising and funding the research?

This study is being funded by the NHS National Institute of Health Research [NIHR] under the Research for Patient Benefit scheme.

Who has reviewed the study?

The research process was reviewed by the NIHR as part of the grant competition process. In addition, the research protocol has been reviewed by the HIP Project Steering Group, which includes mental health service users, mental health nurses and doctors, managers from Norfolk and Waveney Mental Health NHS Foundation Trust, Lincolnshire Partnership NHS Foundation Trust and researchers from the School of Healthcare at the University of East Anglia.

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity.

This study has been reviewed and given favourable opinion by the National Research Ethics Service Cambridge 4 Research Ethics Committee.

Further information and contact details

Further information about the study, including general information about research and specific information about this research project, is available from the Study

Coordinator, Jacquie White:

email: _____

Voicemail: _____

If you would like further independent information to help you decide if you want to take part you may wish to contact the East Anglia Hub of the Mental Health Research Network 01223 746 135

HIP Trial/number date of preparation.

Centre Number:

Study Number:

Nurse Subject Identification Number for this trial:

Nurse CONSENT FORM PART 1

Title of Project: **Cluster randomised controlled trial of the Serious Mental Illness Health Improvement Profile (HIP)**

Name of Principal Investigator: **Professor Richard Gray**, Professor in Research Related to Nursing, & Director of Post Graduate Research, University of East Anglia. Honorary Nurse Consultant, Norfolk and Waveney Mental Health NHS Foundation Trust.

	Please initial box
1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my employment or legal rights being affected.	
3. I understand that relevant sections of patient records completed by me* and data collected during the study, may be looked at by members of the HIP research team at the University of East Anglia and/or from Norfolk and Waveney Mental Health NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. *Access to specific patient records will only take place where the patient has given their written consent to participate in the HIP trial.	
4. I agree to take part in the above study.	

Name of Nurse

Date

Signature

Name of Person
taking consent

Date

Signature

Patient INFORMATION SHEET 1

Title of Project: Cluster randomised controlled trial of the serious mental illness Health Improvement Profile [HIP]

Name of Principal Investigator: Professor Richard Gray, Professor in Research Related to Nursing, & Director of Postgraduate Research, University of East Anglia. Honorary Nurse Consultant, Norfolk and Waveney Mental Health NHS Foundation Trust.

Invitation

We would like to invite you to take part in the HIP research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and decide whether or not you wish to take part. Talk to others about the study if you wish. If you would like copies of this information sheet for your relatives or other people who support you please ask.

Part 1 tells you the purpose of this study and what will happen to you if you take part

Part 2 gives you more detailed information about the conduct of the study

Ask us if there is anything that is not clear or if you would like more information. You can ask your nurse or doctor about the study or contact the Study Coordinator. The Study Coordinator is a mental health nurse, Jacquie White and she can be contacted by email at jacqueline.white@hull.ac.uk or telephone 01482 464537 (voicemail).

PART 1

What is the purpose of the study?

Physical illness in people with serious mental illness is common and sometimes gets overlooked. It is important to find out about physical health problems as many can be treated. We think mental health nurses can help patients recognise and address physical health problems; for example by helping them consider changes to their diet, smoking and the amount of exercise taken to reduce their risk of heart disease. We have developed the Health Improvement Profile [HIP] to help mental health nurses work with patients to find out about physical health problems and choose the next steps to take together.

The purpose of the study is to ascertain whether mental health nurses and patients can find out about physical health problems and plan care together using the HIP. We will also calculate the costs of introducing the HIP and evaluate the experience of patients, nurses, psychiatrists and GPs where the HIP has been used. This research is being carried out as part of a PhD qualification supervised by Professor Richard Gray at the University of East Anglia.

Why have I been invited?

You have been invited to participate because your community mental health nurse has agreed to take part. Across Norfolk, Suffolk and Lincolnshire we are aiming to find at least fifty community mental health nurses and two hundred and fifty patients who are willing to take part so we have enough people to adequately measure if the HIP works.

Do I have to take part?

No - it is up to you to decide. A researcher will describe the study and go through this information sheet, which she/he will then give to you to read. If you want to take part she/he will then ask you to sign a consent form to show you have agreed to participate. If you change your mind at any time you are free to withdraw from the study, without giving a reason. This would not affect the standard of care you receive now or in the future from your nurse, team or the NHS.

What will happen to me if I take part?

If you agree to take part and after you have signed the consent form the researcher will complete a form with some general details about you. This is so we can ensure that the patients who take part in the study are similar to those usually cared for by community mental health nurses.

We will then make an appointment for one of our researchers to interview you. This meeting will take 30 minutes and will take place in a private interview room at a local centre or at your home. In this meeting we will ask you questions about:

1. Services that you currently receive as part of your health and social care
2. Your views about how your physical health impacts on your life

After this meeting we will not interview you again for a year. If your community mental health nurse has been trained to use the HIP she/he will ask you to complete this with him/her as part of the

assessment of your physical health needs and to help you plan care together. Every time this takes place a copy of the HIP form will be sent to the research team.

At the end of a year we will ask whether you still want to continue in the study. If you are still happy to take part we will make an appointment for our researcher to interview you again. This meeting will take 30 minutes in a private interview room or at home as before. In this meeting we will repeat the questions about:

1. Services that you currently receive as part of your health and social care
2. Your views about how your physical health impacts on your life

After this final meeting with the researcher, if you were in the group of patients whose nurse was trained to use the HIP with you we may look back at your patient record over the last year to see if evidence has been recorded of your physical health needs and care provided. The sort of evidence we will look at will include care plans and any letters about your physical health to other people or services e.g. letters to your GP.

Research Method

At present, we are uncertain as to which is the best method of ascertaining needs and planning appropriate physical health care. To discover this, we need to compare the different approaches and this will be done by researchers putting people into groups, each group using a different approach. The results are then compared to see if one is better than the other. To ensure the random composition of the groups, each person will be allocated by chance.

The HIP research study is called a 'cluster randomised controlled trial'. The nurses who agree to take part in this study are randomly put into groups to either receive the HIP training or carry on providing care as usual; only half of all the nurses in the study will receive the HIP training. Computer software will be used to make sure each nurse has an equal chance of being allocated to the 'HIP' or 'Usual Care group'. The word 'cluster' is used because it is the nurses and not the patients who are put into groups. It follows, that for the year, only half of the patients in the study will use the HIP.

After a year a researcher will look at the patient record for a sample of 36 patients in the HIP group to see how physical care given to these patients whose nurses received the HIP training was recorded. Looking in the patient record for evidence of the quality of care received is called an audit.

Expenses and payments

Over the course of the next year we are asking you to attend two additional appointments with a researcher. We do not want this to cause you any financial problems, so we will either arrange travel for you or arrange to pay your expenses. The researcher who visits you will help you claim any costs back from us.

What will I have to do?

We will expect you to attend the two study meetings arranged with the researcher and answer questions as accurately as you can. If your circumstances change in between the yearly appointments, we will expect you to let your nurse know (e.g. your contact details if you move). If for any reason you wish to withdraw from the study, we will expect you to tell either your nurse, psychiatrist or the research team (contact number).

What is the procedure that is being tested?

The HIP was developed in the UK by a team of three mental health nurses after a review of the physical health problems experienced by people with serious mental illness. It is the purpose of this study to test the validity of the Health Improvement Profile [HIP]. Early studies with small numbers of nurses and patients improved the HIP (e.g. it was decided it was easier to use if it was made to fit on one side of paper). A workshop was designed to train nurses to use the HIP with patients, and one of the first mental health nurses trained used the HIP in an outpatient clinic in Scotland and completed it with 31 patients. The patients, nurses and doctors in Scotland told us they liked the tool and said it helped them find out problems and together, plan care. If we are to be certain that the HIP works well we need to use it with much larger numbers of nurses and patients.

What are the alternatives for diagnosis or treatment?

The alternative is to continue receiving care from your community mental health team as you do at the moment. All mental health teams offer assessment and treatment to meet a whole range of health and social care needs. If you are worried about your physical health it is always sensible to discuss your concerns with your community mental health nurse, psychiatrist and/or GP.

What are the possible disadvantages and risks of taking part?

You may be inconvenienced by the extra time required to attend the two interviews. Use of the HIP may mean you find out about a physical health problem of which you were unaware and this may worry you. Nurses trained to use the HIP may need more time, when visiting you, to complete the HIP and plan your care. The next steps recommended in the HIP may include going to extra appointments (e.g. with other health professionals) and/or being asked to have additional tests (e.g. blood tests). However, you can discuss this further with your nurse and/or doctor and decide, at the time, if you wish to proceed.

What are the possible benefits of taking part?

We cannot promise the study will help you personally, but the information gained will help the NHS work out the best ways to work with patients and look after their physical health. You may find taking part in the study means you and your nurse will discover more about your physical health. This may help you make choices about what to do if you have a problem or to prevent problems happening in the future. If the study is successful you will have taken part in a project, which will have a positive impact on the lives of many other patients.

What happens when the research study stops?

At the end of the study you will continue to receive care as usual. Norfolk and Waveney Mental Health NHS Foundation Trust has agreed to continue to support the use of the HIP if the trial is successful. At the end of the study, if your nurse did not receive the HIP training, he/she will be invited to attend a HIP training workshop.

We are also interested to know how the use of the HIP may affect the planned care and the opinions of patients, nurses and doctors regarding the HIP. If your nurse was in the HIP trained group, we may invite you to take part in this part of the study. We will ask you separately about this extra part of the study nearer the time and provide a separate information sheet and consent form.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What if relevant new information becomes available?

Sometimes when we are doing research we get new information about the approach being studied. If this happens, your nurse will tell you and ask you if you want to carry on in the study. If you decide not to, your care will continue as before. If you decide to continue in the study you may be asked to sign a new consent form. If the study is stopped for any reason, we will tell you and arrange for your care to continue as before.

What will happen if I don't want to carry on with the study?

If you wish to stop taking part in the study for any reason at all, please let your nurse, psychiatrist or the research team know (contact number). You will not then need to do anything else and your care will continue as it was before the study.

What will happen if I lose the capacity to consent to continue in the study after it has started?

If you lose the capacity to consent to continue in the study the research team will withdraw you from the study and we will inform you and the clinical team who care for you we are doing this. You will not then need to do anything else and your care will continue as it was before the study.

If you stop taking part after the first interview for any reason at all the information that was collected will still be analysed and incorporated with the other patients' information. However, no more information will be added about you after you have withdrawn.

What if there is a problem?

If you have a concern about any part of the study, you should ask to speak to a member of the research team who will do their best to answer your questions (contact number). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your nurse or doctor or via the local Patient Advice and Liaison Service [PALS] Tel: 0800 585544 or email them at pals@smhp.nhs.uk

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What if a member of the research team believes they have observed poor practice or has concerns about possible poor practice reported to them?

Any poor practice concerns about participants or any other member of the care team will be reported to the appropriate line manager and followed up in writing within 24 hours.

Will my taking part in this study be kept confidential?

All information collected for the HIP study from you or your nurse will be recorded on forms that are given a unique study number. Your name, address or NHS number will not be written on the forms. This is to make sure that information collected about you does not identify you or your nurse but can be traced back to the group that your nurse was put in at the beginning of the study (the HIP training group or the Usual Care group). All members of the HIP research team at the University of East Anglia will have access to this anonymous data.

The Consent Forms are the only forms that identify the patients, nurses and doctors in the study by name. These will be kept in a locked filing cabinet within a locked office at the research team base at the University of East Anglia together with details of the unique study code numbers. In the unlikely event of a problem, only the Principal Investigator and the Study Coordinator will be able to access the cabinet. This will enable them to break the study code and contact you or your nurse, psychiatrist, GP or Care Coordinator. Should this occur, you will of course be informed.

All the information collected during the trial will be stored securely for a period of 5 years, after which time it will be destroyed.

NHS Research Governance staff can inspect all information collected during the study at any time to check the research has been carried out correctly. All staff taking part in inspections must keep the highest standards of confidentiality at all times.

Involvement of your Psychiatrist, Care Coordinator and General Practitioner/Family doctor (GP)

After consenting to take part, we will inform your psychiatrist, care coordinator and GP that you are participating in the HIP research study by letter. Your nurse will continue to talk to these other health professionals as they do now regarding your care.

What will happen to the results of the research study?

As soon as we have the results we will send out a newsletter to share our findings with everyone who participated. We started recruitment for the HIP study in April 2011 and we plan to complete all the study work and be ready to report the results after three years.

Reports and presentations will be written by the research team thus allowing the results to be shared as widely as possible. These publications and presentations will not identify any nurse, patient or team by name.

Who is organising and funding the research?

The study is being financed by the NHS National Institute of Health Research [NIHR] under the Research for Patient Benefit scheme.

Who has reviewed the study?

An application for financial support was made after the Research Plan had been reviewed by the national NIHR experts. The research plan has also been reviewed by the HIP Project Steering

Group; group members included mental health service users, mental health nurses and doctors, managers from Norfolk and Waveney Mental Health NHS Foundation Trust, Suffolk Mental Health Partnership NHS Trust, Lincolnshire Partnership NHS Foundation Trust and researchers from the School of Nursing Sciences at the University of East Anglia.

All research within the NHS is scrutinized by a Research Ethics Committee, an independent group set up to protect your safety, rights, wellbeing and dignity. This study has been reviewed and favourably received by the National Research Ethics Service Cambridge 4 Research Ethics Committee.

Further information and contact details

Further information about the study including general information about research and specific information about this research project in particular is available from the Study Coordinator, Jacquie White email: jacqueline.white@hull.ac.uk Voicemail: 01482464537.

If you would like further independent information to help you decide if you want to take part you may wish to contact:

Patient Advice Liason Service (PALS),
Suffolk Mental Health Partnership NHS Trust
Suffolk House, St Clements Hospital, Foxhall Road, Ipswich, Suffolk IP3 8LD

email: pals@smhp.nhs.uk

Patient Information Sheet 1 HIP/number date of preparation.

A copy of this information sheet and the signed consent form have been given to the patient

Centre Number:

Study Number:

Patient Identification Number for this trial:

Patient CONSENT FORM

Title of Project: **Cluster randomised controlled trial of the Serious Mental Illness Health Improvement Profile (HIP): Part 1**

Name of Principal Investigator: **Professor Richard Gray**. Professor in Research Related to Nursing, & Director of Postgraduate Research, University of East Anglia. Honorary Nurse Consultant, Norfolk and Waveney Mental Health NHS Foundation Trust

	Please initial box
1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by members of the HIP research team at the University of East Anglia and/or from Norfolk and Waveney Mental Health NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree to my GP, Care Coordinator and Psychiatrist being informed of my participation in the study	
5. I agree to take part in the above study.	

_____	_____	_____
Name of Patient	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

Centre Number:

Study Number:

Patient INFORMATION SHEET 2

Title of Project: HIP Trial Part 2

Name of Principal Investigator: Professor Richard Gray, Professor in Mental Health, University of the West of England and Honorary Nurse Consultant, Avon and Wiltshire Mental Health Partnership NHS Trust.

Invitation

We would like to invite you to take part in an additional part of the HIP research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and decide whether or not you wish to participate. Talk to others about the study if you wish. If you would like copies of this information sheet for your relatives or other people who support you please ask.

Part 1 tells you the purpose of this study and what will happen to you if you take part

Part 2 gives you more detailed information about the conduct of the study

Ask us if there is anything that is not clear or about which you would like more information. You can ask your nurse or doctor about the study or contact the Process Observation Lead or Study Coordinator. Both of these researchers are mental health nurses, Richard Sly is based at the University of east Anglia in Norwich and Jacquie White at the University of Hull and they can be contacted either by email HIP@uea.ac.uk or telephone 01603 597196 or 01482 464537.

PART 1

What is the purpose of the study?

Physical illness in people with serious mental illness is common and sometimes gets overlooked. It is important to find out about physical health problems as many can be treated. We developed the Health Improvement Profile [HIP] to help mental health nurses when working with patients, to identify physical health problems and decide the next steps to take. We have been comparing the physical care of patients cared for by nurses trained in the use of the HIP with another group of patients whose nurses who did not receive this training.

We now want to find out if using the HIP improved the quality of care that was planned and delivered and what everyone involved thought about the HIP. This research is being carried out as part of a PhD qualification supervised by Professor Richard Gray at the University of East Anglia and the West of England.

Why have I been invited?

You have been invited to participate because you took part in the HIP study and your mental health nurse was in the group of nurses trained to use the HIP. We intend to recruit at least ten patients from across Norfolk and Lincolnshire to take part in interviews about their experiences.

Do I have to take part?

No - it is up to you to decide. If you are interested the Study Coordinator will arrange for a researcher to see you either in a private interview room at a local centre or at your home to describe the study and go through this information sheet with you, which they will then give to you to read. If you want to take part they will then ask you to sign a consent form to indicate your agreement. If, at any time you change your mind about taking part, you are able to withdraw without giving a reason. This will not affect the standard of care you receive now or in the future from your nurse, care team or the NHS.

What will happen to me if I take part?

If you agree to take part, and after you have signed the consent form, the researcher will ask you a series of questions. This interview will take about 30 minutes and will include questions about:

1. What you think about the HIP
2. What effect, if any, you think it had on the care that was planned with you and the care you received.

The researcher will take notes to summarise what you say in the interview. They will ask you to check that you agree with what they have noted at the end of the interview so we can accurately type up what was said later. This will allow us to compare and summarise the comments made by all of the participants in all ten interviews.

Research Method

This part of the HIP study is called a 'Process Observation'. As yet we do not know enough about the use of the HIP in practice (the process) and want to find out (observe) what it was like for those who used it and if it had any impact on their physical health care. To do this we will interview patients, their nurses, psychiatrists and General Practitioners [GPs] and record and analyse their views. This will enable us to make comparisons and identify any common experiences, so that lessons can be learned about the use of the HIP.

Expenses and payments

As you will be invited to attend an additional appointment we would not want this to cause you any financial problems. We will either arrange your travel or pay reasonable travel expenses for your journey to and from the interview.

What will I have to do?

We will expect you to attend the meeting and answer questions as accurately as you can. We will also expect you to agree to the researcher taking notes and typing these up later (transcription). They will ask you to look at the notes first to make sure you agree they are an accurate reflection of what you said.

What is the procedure that is being tested?

After a review of the physical health problems experienced by people with serious mental illness, a team of three UK mental health nurses developed the HIP and it is now the subject of this study. Early studies with small numbers of nurses and patients refined the HIP (e.g. if it was designed to fit on one side of paper it became easier to use). A workshop was set up to train nurses to use the HIP with patients. One of the first mental health nurses to be trained used the HIP (in an outpatient clinic in Scotland) with 31 patients. The patients, nurses and doctors told us they liked the tool and said it helped them diagnose problems and plan care. To be confident that the HIP works it is necessary to trial it with larger numbers of nurses and patients - this was the first part of the study. The Process Observation study is being carried out to establish what it was like to use the HIP and ascertain whether it made a difference to care.

What are the alternatives for diagnosis or treatment?

The alternative is to continue, as at present, receiving care from your community mental health team. All mental health teams offer assessment and treatment to meet the whole range of health and social care needs. If you are concerned about your physical health it is always advisable to discuss these worries with your community mental health nurse, psychiatrist and/or GP.

What are the possible disadvantages and risks of taking part?

You may be inconvenienced by the extra time required to attend the group interview with the Study Coordinator.

What are the possible benefits of taking part?

We cannot promise that the study will help you personally but the information we collect will help the NHS determine how best to work with patients and look after their physical health. Your views regarding the care you received from an HIP trained nurse, together with information from your notes, will enable us to make recommendations concerning the use of HIPs in the future.

What happens when the research study stops?

At the end of this part of the study you will continue to receive care as usual. Norfolk and Suffolk NHS Foundation Trust has agreed to continue to support the use of the HIP if the study is successful.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What if relevant new information becomes available?

Sometimes when we are doing research we get new information about the approach being studied. If this happens, your nurse will tell you and ask if you wish to continue in the study. If you decide not to, your care will continue as before. If you decide to continue you may be asked to sign a new consent form. If the study is stopped for any reason, we will tell you and arrange for your care to continue as before.

What will happen if I don't want to carry on with the study?

If you wish to stop taking part in the study for any reason at all, please let your nurse, psychiatrist or the research team know (on 01603 597196, 01482 464537). You will not then need to do anything else and your care will continue as it was before the study.

If you stop taking part after the first interview the information that was collected will still be analysed and incorporated with the other patients' information. However, no more information will be added about you after you have withdrawn.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions (on 01603 597196, 01482 464537). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your nurse or doctor or via the local Patient Advisory and Liaison Service [PALS] Tel: 0800 279 7257 email: pals@nsft.nhs.uk

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What if a member of the research team believes they have observed poor practice or has concerns about possible poor practice reported to them?

Any poor practice concerns about participants or any other member of the care team will be reported to the appropriate line manager and followed up in writing within 24 hours.

Will my taking part in this study be kept confidential?

All information collected for the HIP study from you or your nurse will be recorded on forms that are given a unique study number. Your name, address or NHS number will not be written on the forms. This is to make sure that information collected about you does not identify you or your nurse but can be traced back to the group that your nurse was put in at the beginning of the study (the HIP training group or the Care as Usual group). All members of the HIP research team will have access to this anonymous data.

The Consent Forms are the only forms that identify the patients, nurses and doctors by name. These will be kept in a locked filing cabinet within a locked office at the research team base at the University of East Anglia together with details of the unique study code numbers. In the unlikely event of a problem, only the Principal Investigator and the Study Coordinator will be able to access the cabinet. This will enable them to break the study code and contact you or your nurse, psychiatrist, GP or care Coordinator. Should this occur, you will of course be informed.

All the information collected during the trial will be stored securely for a period of 5 years, after which time it will be destroyed.

NHS Research Governance staff can inspect all information collected during the study at any time to check the research has been carried out correctly. All staff taking part in inspections must keep the highest standards of confidentiality at all times.

Involvement of your Psychiatrist, Care Coordinator and General Practitioner/Family doctor (GP) Involvement of your Psychiatrist, Care Coordinator and General Practitioner/Family doctor (GP)

After consenting to take part, we will inform your psychiatrist, care coordinator and GP that you are participating in the HIP study. Your nurse will continue to talk to these other health professionals as they do now regarding your care.

What will happen to the results of the research study?

As soon as we have the results we will send out a newsletter to share our findings with everyone who participated. We started recruitment for the HIP study in May 2011 and we plan to complete all the study work and be ready to report the results after three years.

Reports and presentations will be written by the research team thus allowing the results to be shared as widely as possible. These publications and presentations will not identify any nurse, patient or team by name.

Who is organising and funding the research?

The study is being funded by the NHS National Institute of Health Research [NIHR] under the Research for Patient Benefit scheme.

Who has reviewed the study?

An application for financial support was made after the Research Plan had been reviewed by the national NIHR experts. The research plan has also been reviewed by the HIP Project Steering Group; group members included mental health service users, mental health nurses and doctors, managers from Lincolnshire Partnership NHS Foundation Trust, Norfolk and Suffolk NHS Foundation Trust and researchers from the School of Nursing Sciences at the University of East Anglia.

All research within the NHS is scrutinised by a Research Ethics Committee, an independent group set up to protect your safety, rights, wellbeing and dignity. This study has been reviewed and favourably received by the National Research Ethics Service Cambridge South Research Ethics Committee.

Further information and contact details

Further information about the study including general information about research and specific information about this research project in particular is available from the Study Coordinator, Jacquie White email: HIP@uea.ac.uk Voicemail: 01603 597196 or 01482 464537.

If you would like further independent information to help you decide if you want to take part you may wish to contact:

Patient Advice Liason Service (PALS), Norfolk and Suffolk NHS Foundation Trust, Hellesdon Hospital, Drayton High Road, Norwich, NR6 5BE
Tel: 0800 279 7257, email: pals@nsft.nhs.uk

Patient Information Sheet Appendix 5.4 Patient Information Part 2 v4_22_02_2013 NSFT

A copy of this information sheet and the signed consent form have been given to the patient



Centre Number:

Study Number:

Patient Identification Number for this trial:

Patient CONSENT FORM

Title of Project: **Cluster randomised controlled trial of the Serious Mental Illness Health Improvement Profile (HIP): Part 2**

Name of Principal Investigator: **Professor Richard Gray**. Professor in Research Related to Nursing, & Director of Postgraduate Research, University of East Anglia. Honorary Nurse Consultant, Norfolk and Waveney Mental Health NHS Foundation Trust

	Please initial box
1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that the interview will be tape recorded, for later transcription and analysis.	
4. I agree to my GP, Care Coordinator and Psychiatrist being informed of my participation in the study	
5. I agree to take part in the above study.	

Name of Patient

Date

Signature

_____ Name of Person taking consent	_____ Date	_____ Signature
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When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

**Cluster Randomised Controlled Trial of the Serious Mental Illness Health
Improvement Profile (HIP)
Part 2**

Centre Number:

Study Number:

Principal Investigator:

Professor Richard Gray, Professor in Mental Health, University of the West of England Faculty of Health and Life Sciences 2G01 Glenside, UWE, Bristol BS16 1DD. Honorary Nurse Consultant, Avon and Wiltshire Mental Health Partnership NHS Trust.

Trial Coordinator:

Jacquie White, Faculty of Health, Edith Cavell Building, University of East Anglia, Norwich NR4 7TJ and 209 Dearne Building, University of Hull, Cottingham Road, Hull. HU6 7RX.

Organisations involved:

University of East Anglia
Norfolk and Suffolk NHS Foundation Trust
Lincolnshire Partnership NHS Foundation Trust
South Essex Partnership University NHS Foundation Trust

Funded by:

National Institute for Health Research: Research for Patient Benefit Programme, East of England

PART 1

What is the purpose of the trial?

As a nurse who has been involved in Part 1 of the trial, you will be aware that the development of the HIP is an attempt to help mental health nurses work with patients to identify physical health problems and select the appropriate next steps to take.

This is Part 2 of the HIP trial. It will evaluate the experience of patients, nurses, psychiatrists and GPs, where nurses were trained to use the HIP and also look to see if there was any impact on the care planned and delivered.

What is the procedure that is being tested?

The Health Improvement Profile [HIP] tool is being tested.

In the information sheet to Part 1 of this trial, we told you that the HIP was developed in the UK by a team of three mental health nurses following a review of the physical health problems experienced by people with serious mental illness.

Early 'pilot' studies with small numbers of nurses and patients refined the tool (e.g. it was decided it was easier to use if it was made to fit on one side of paper). A training workshop was developed to train nurses to use the HIP in their practice.

One of the first mental health nurses to be trained introduced the HIP into an outpatient clinic in Scotland and completed it with 31 patients. This demonstrated it could successfully identify physical health problems. The patients, nurses and doctors told us they liked the tool and said it helped them plan care together.

To be really certain that the HIP had a positive impact on the physical health outcomes of patients we needed to measure the outcomes in much larger numbers of nurses and patients in a randomised controlled trial.

To find out more about what it was like to use the HIP in practice and if it had an impact on care we now need to carry out an additional part of the study called a Process Observation. Part 1 and 2 of this research is being carried out as part of a PhD qualification supervised by Professor Richard Gray at the University of East Anglia and the West of England.

Research Method

Part 2 of the trial is a 'Process Observation'.

We don't know enough about how the HIP is used in practice (the process) and want to find out (observe) what it was like for those who used it. If it had any impact on the physical health care planned and delivered.

To do this we will collect qualitative and quantitative data.

We will interview patients, psychiatrists, nurses and GPs and record their views. This will allow us to compare what they tell us to see if there are any common experiences of the process.

We will also audit the mental health trust notes of a sample of patients to see if using the HIP has had an effect on the care planned and delivered over the last year.

Why have I been invited?

You have been invited to take part because you took part in the original HIP trial and were trained to use the HIP.

We now want to find out what this experience was like for everyone involved and if it made a difference to the care planned and delivered to patients.

Across the whole of Norfolk and Suffolk NHS Foundation Trust, we are aiming to find five Community Mental Health Nurses who have been using the HIP to interview . With nurses we also aim to interview across Lincolnshire this will provide a sample of 10 nurses in total.

Do I have to take part?

If you agree to take part, and after you have signed the consent form, you will participate in an interview with the Process Observation Lead at your team base or other location convenient to you. The Process Observation Lead is called Dr Richard Sly and he is a Lecturer and Mental Health Nurse based at the University of East Anglia.

This meeting will take 40 minutes and will take place in a private room.

In this meeting we will ask you all questions about:

1. What you think about the HIP
2. Your experience of implementing the HIP in your practice
3. What effect, if any, you think it had on the care that was planned by you with your patients
4. What effect, if any, you think it had on the care your patients' received.

The interview will be recorded so we can later type up what was said.

This will allow us to collect, compare and summarise what you and other health professionals say about your experiences and see if any common themes emerge (content analysis).

What will I have to do?

We will ask you to attend the interview and answer questions as accurately as you can. We will also ask you to agree to this interview being recorded (taped) and typed up later (transcribed).

What are the possible disadvantages and risks of taking part?

You may be inconvenienced by the extra time required to attend the focus group..

What are the possible benefits of taking part?

Your views about what it was like to use the HIP after training and the information from the audit will enable us to make recommendations about how the HIP can be best used by nurses and patients in the future.

The information gained by the trial may help the NHS work out the best way to work with mental health patients to find out about physical health problems, which might otherwise go undetected.

If the study is successful, you will have been part of a research trial which may have a positive impact on the lives of many patients.

What happens when the research trial stops?

Norfolk and Suffolk NHS Foundation Trust has agreed to continue to support the clinical use of the HIP in practice if the study is successful.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the trial be kept confidential?

We will follow ethical and legal practice and all information about you will be anonymised. The details are included in Part 2.

This completes Part I.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What if relevant new information becomes available?

Sometimes when we are doing research we get new information about the approach being studied. If this happens, the Trial Coordinator will tell you and discuss whether you should continue in the trial. If you do decide to continue, they may ask you to sign an updated consent form. If the trial is stopped for any reason, we will tell you why.

What will happen if I don't want to carry on with the trial?

If you change your mind and wish to stop taking part in the trial, before the focus group for any reason at all, please let the research team know (on 01603 597196, 01482 464537 or 07775 904592) and they will withdraw you from the trial.

What if there is a problem?

If you have a concern about any aspect of this trial, you should ask to speak to a member of the research team, who will do their best to answer your questions (on 01603 597196, 01482 464537 or 07775 904592). If you remain unhappy and wish to complain formally, you can do this through your line manager and/or the Research and Development Team in Norfolk and-Suffolk NHS Foundation Trust 01603 421340.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What if a member of the research team believes they have observed poor practice or has concerns about possible poor practice reported to them?

Any poor practice concerns about participants or any other member of the care team will be reported to the appropriate line manager and followed up in writing within 24 hours.

Will my taking part in this study be kept confidential?

All information collected for this part of the study will be recorded on forms which are given a unique study number. They will not include your name or work address. This includes the transcript of what is said in the focus group interview. If you inadvertently mention names or work addresses in the focus group, these will be removed at the typing up stage. This is to make sure that information collected for the study does not individually identify you, your patients, other nurses taking part or doctors. All members of the HIP research team at the University of East Anglia will have access to the anonymised data.

The Consent Forms are the only forms which identify patients, nurses and doctors in the study by name. These will be kept in a locked filing cabinet within a locked office at the research team base at the University of East Anglia, alongside details of the unique study code numbers and the recordings (tapes), once they have been typed up. Only the Principle Investigator and the Trial Coordinator will be able to access this cabinet. This is in case there is a problem and we need to break the study code to enable us to contact you or your patients. If this happens we will tell you.

All the information collected during the trial will be archived at the end of the trial and kept in a secure room at the University of East Anglia for 5 years. After 5 years it will be destroyed securely.

All information collected and stored during the study and afterwards may be inspected by NHS Research Governance staff at any time to make sure the research process has been carried out

correctly. All staff participating in inspections must maintain the highest standards of confidentiality at all times.

Involvement of your line manager

We will ask you to inform your line manager that you are participating in the Process Observation part of the HIP trial.

What will happen to the results of the research trial?

As soon as we have the results, we will send out a newsletter to share our findings with everyone who took part. We started recruitment for the HIP trial in May 2011 and we plan to complete all the trial work and be ready to report the results after three years.

Reports and presentations will be written by the research team to enable the results to be shared as widely as possible. These publications and presentations will not identify any nurse, patient or team by name.

Who is organising and funding the research?

This trial is being funded by the NHS National Institute of Health Research [NIHR] under the Research for Patient Benefit competition grant scheme.

Who has reviewed the trial?

The research process was reviewed by the NIHR as part of the grant competition process. In addition, the research protocol has been reviewed by the HIP Trial Steering Group which includes mental health service users, mental health nurses and doctors, managers from Lincolnshire Partnership NHS Foundation Trust, Norfolk and Suffolk NHS Foundation Trust and researchers from Nursing Sciences at the University of East Anglia.

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This trial has been reviewed and given favourable opinion by the National Research Ethics Service Cambridge South Research Ethics Committee.

Further information and contact details

Further information about the study including general information about research and specific information about this research project is available from the Trial Coordinator, Jacquie White:

Email: HIP@uea.ac.uk

Voicemail: 01603 597196, 01482 464537 or 07775 904592

If you would like further independent information to help you decide if you want to take part you may wish to contact:

East Anglia Hub of the Mental Health Research Network 01223 746 135

Nurse Information Sheet HIP Trial App 5.2 Nurse Information Part 2 v4_22_02_2013 NSFT

A copy of this information sheet and the signed consent form have been given to the nurse subject.

Centre Number:

Study Number:

Nurse Subject Identification Number for this trial:

Nurse CONSENT FORM PART 2

Title of Project: **Cluster randomised controlled trial of the Serious Mental Illness Health Improvement Profile (HIP)**

Name of Principal Investigator: **Professor Richard Gray**, Professor in Research Related to Nursing, & Director of Post Graduate Research, University of East Anglia. Honorary Nurse Consultant, Norfolk and Waveney Mental Health NHS Foundation Trust.

	Please initial box
1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my employment or legal rights being affected.	
3. I understand the focus group discussions will be audio taped for later transcription and analysis	
4. I agree to take part in the above study.	

Name of Nurse Date Signature

Name of Person Date Signature
taking consent

**Cluster Randomised Controlled Trial of the Serious Mental Illness
Health Improvement Profile (HIP)
Part 2**

Information for General Practitioners and Psychiatrists

Chief Investigator:

Professor Richard Gray, Professor in Mental Health, School of Nursing and Midwifery, University of the West of England, Bristol.

Trial Co-ordinator:

Jacquie White, School of Nursing Sciences, Edith Cavell Building, University of East Anglia, Norwich Research Park, Norwich NR4 7TJ.

Organisations involved in the trial:

- Norfolk and Suffolk NHS Foundation Trust
- Lincolnshire Partnership NHS Foundation Trust
- South Essex Partnership University NHS Foundation Trust
- University of East Anglia

Funded by:

National Institute for Health Research: Research for Patient Benefit Programme, East of England.

PART 1

What is the purpose of the study?

We have developed a tool called the Health Improvement Profile (HIP) to help mental health nurses work with patients to identify physical health problems and select the appropriate next steps to take.

This is Part 2 of the HIP study. It will evaluate the experience of patients, nurses, psychiatrists and GPs, where nurses were trained to use the HIP and also look to see if there was any impact on the care planned and delivered. Part 1 and 2 of this research is being carried out as part of a PhD qualification supervised by Professor Richard Gray (the Chief Investigator).

What is the procedure that is being tested?

The Health Improvement Profile (HIP) tool is being tested. This tool was developed in the UK by a team of three mental health nurses following a review of the physical health problems experienced by people with serious mental illness. Early pilot studies with small numbers of nurses and patients further refined the tool.

A training workshop was developed to train nurses to use the tool in their practice.

One of the first mental health nurses to be trained introduced the HIP into an outpatient clinic in Scotland and the tool was completed with 31 patients. This demonstrated it could successfully identify physical health problems.

The patients, nurses and doctors told us they liked the tool and said it helped them plan care together. To be really certain that the HIP has a positive impact on the physical health outcomes of patients, we now need to measure the outcomes in much larger numbers of nurses and patients in a randomised controlled trial.

To find out more about what it was like to use the HIP in practice and if it had an impact on care we need to carry out an additional part of the study called a Process Observation.

Why have I been invited?

You have been invited to take part because one of the patients you work with is cared for by a nurse who has had the HIP training.

We now want to find out what this experience was like for everyone involved and if it made a difference to the care planned and delivered to patients. Across the whole of Norfolk and Suffolk NHS Foundation Trust, Lincolnshire Partnership NHS Foundation Trust and South Essex Partnership University NHS Foundation Trust we are aiming to interview (by phone) ten GPs and psychiatrists whose patients have been involved in the trial.

Do I have to take part?

No - it is up to you to decide. The trial coordinator will send you this information to read with a letter asking you if you are interested in taking part in a telephone interview. If you agree to take part, she will ask you to confirm this and then sign a consent form

If you change your mind at any time you are free to cancel your participation without giving a reason.

What happens if I take part?

If you agree to take part in a telephone interview, we would like you to return the response slip, with details of when it would be convenient to contact you for the interview. We would also ask you to complete the consent form and return it with the response slip.

The Trial Co-coordinator will then phone you at the specified time and check that you continue to consent and it is still convenient to do the interview.

The interview will be recorded and then transcribed.

During the interview, you will be asked:

1. What you think about the HIP
2. Your experience of any implications the HIP has had for your practice
3. What effect, if any, you think it had on the care that was planned by you with your patients
4. What effect, if any, you think it had on the care your patients received.

Research Method

This part of the HIP study is called a 'Process Observation'.

We don't know enough about how the HIP is used in practice (the process) and want to find out (observe) what it was like for those who used it. If it had any impact on the physical health care planned and delivered. To do this we will collect qualitative and quantitative data.

We will interview patients, nurses, psychiatrists and GPs and record their views. This will allow us to compare what they tell us, to see if there are any common experiences of the process. We will also audit the mental health service patient record of a sample of patients to see if using the HIP has had an effect on the care planned and delivered over the last year.

What will I have to do?

We would like you to participate in a telephone interview with the Trial Co-ordinator, answering questions as accurately as possible. We would also like you to agree to the conversation being recorded and transcribed.

What are the possible disadvantages and risks of taking part?

You may be inconvenienced by the time required to consider and participate in a telephone interview with the Trial Co-coordinator.

What are the possible benefits of taking part?

Your views about the HIP and the information from the audit will enable us to make recommendations about how the HIP can be best used by nurses and patients in the future.

The information gained by the trial may help the NHS work out the best way to work with mental health patients to find out about physical health problems, which might otherwise go undetected.

If the study is successful, you will have been part of a research trial which may have a positive impact on the lives of many patients.

What happens when the research study stops?

As soon as we have the results, we will send out a newsletter to share our findings with everyone who took part.

Norfolk and Suffolk NHS Foundation Trust has agreed to continue to support the clinical use of the HIP in practice if the study is successful.

What if there is a problem?

Any complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What if relevant new information becomes available?

Sometimes when we are doing research we get new information about the approach being studied. If this happens, the Trial Coordinator will tell you and discuss whether you need to participate in the interview. If you decide to continue, she may ask you to sign an updated consent form.

If the trial is stopped for any reason, we will tell you why.

What will happen if I don't want to participate in an interview?

If you change your mind and wish to cancel the interview with the Trial Co-ordinator for any reason at all, please let the research team know (01482 464537) and they will withdraw you from the trial.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team, who will do their best to answer your questions (01482 464537). If you remain unhappy and wish to complain formally, you can do this through the Research and Development Department, Norfolk and Suffolk NHS Foundation Trust, The Knowledge Centre, Hellesdon Hospital, Drayton High Road, Norwich NR6 5BE.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What if a member of the research team believes they have observed poor practice or has concerns about possible poor practice reported to them?

Any poor practice concerns about participants or any other member of the care team will be reported to the appropriate line manager and followed up in writing within 24 hours.

Will my taking part in this study be kept confidential?

All information collected for this part of the study will be recorded on forms which are given a unique study number. They will not include your name or work address. This includes what is said in the telephone interview. If you inadvertently mention names or work addresses in the interview, these will be removed at the typing up stage. This is to make sure that information collected for the trial does not individually identify patients or nurses taking part, or doctors. All members of the HIP research team at the University of East Anglia will have access to the anonymised data.

The Consent Forms are the only forms which identify patients, nurses and doctors in the study by name. These will be kept in a locked filing cabinet within a locked office at the research team base at the University of East Anglia, alongside details of the unique study code numbers and the recordings (digital files), once they have been typed up. Only the Principle Investigator and the Trial Coordinator will be able to access this cabinet. This is in case there is a problem and we need to break the trial code to enable us to contact you or your patients. If this happens we will tell you.

All the information collected during the trial will be archived at the end of the trial and kept in a secure room at the Norfolk and Suffolk NHS Foundation Trust for 5 years. After 5 years it will be destroyed securely.

All information collected and stored during the study and afterwards may be inspected by NHS Research Governance staff at any time to make sure the research process has been carried out correctly.

All staff participating in inspections must maintain the highest standards of confidentiality at all times

What will happen to the results of the research study?

As soon as we have the results, we will send out a newsletter to share our findings with everyone who took part. We started recruitment for the HIP study in May 2011 and we plan to complete all the trial work and be ready to report the results after three years.

Reports and presentations will be written by the research team to enable the results to be shared as widely as possible. These publications and presentations will not identify any nurse, patient or team by name.

Who is organising and funding the research?

This study is being funded by the NHS National Institute of Health Research (NIHR) under the Research for Patient Benefit competition grant scheme.

Who has reviewed the study?

The research process was reviewed by the NIHR as part of the grant competition process.

In addition, the research protocol has been reviewed by the HIP Project Steering Group which includes mental health service users, mental health nurses and doctors, managers from Norfolk and Suffolk NHS Foundation Trust, Lincolnshire Partnership NHS Foundation Trust, and South Essex Partnership University NHS Foundation Trust, and researchers from the School of Nursing Sciences at the University of East Anglia.

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the National Research Ethics Service Cambridge South Research Ethics Committee.

Further information and contact details

Further information about the trial including general information about research and specific information about this research project is available from the Trial Coordinator:

Jacquie White:
Telephone: 01482 464537
Email: jacqueline.white@hull.ac.uk

If you would like further independent information to help you decide if you want to take part you may wish to contact the East Midland Hub of the Mental Health Research Network (0115 823 1302).

Appendix 5

Adapted PHASe nurse characteristics

Table: Characteristics of nurses who completed the adapted PHASe

Adapted PHASe returned		Baseline n=51 unless stated	53 weeks n=21 unless stated	Baseline and 53 weeks n=19 unless stated
Number of CMHNs		n(%) or mean (sd)	n(%) or mean (sd)	n(%) or mean (sd)
GROUP				
HIP Programme Group		27(53%)	8(38%)	7(36%)
TAU Group		24(47%)	13(62%)	12(63%)
NHS Site	1	24(47%)	12(5%)	11(57%)
	2	8(4%)	2(9%)	2(10%)
	3	6(2%)	3(14%)	2(10%)
	4	13(25%)	4(19%)	4(19%)
CMHT Type				
Recovery		31(61%)	11(52%)	11(58%)
Assertive Outreach		16(31%)	7(33%)	6(31%)
Rehabilitation		1(2%)	0(0%)	0(0%)
Forensic		3(6%)	3(14%)	2(10%)
Age in years at consent		45.6 (7.8)	46.1 (8.2)	47.1 (7.5)
Gender	Female	36(70%)	12(57%)	11(58%)
Ethnicity	White British	45(88%)	17(81%)	15(79%)
Grade				
Band 5		1(2%)	0(0%)	0(0%)
Band 6		45(88%)	19(90%)	17(89%)
Band 7		5(10%)	2(9%)	2(10%)
Highest Academic level				
Certificate		11(22%)	5(24%)	5(26%)
Diploma		14(27%)	7(33%)	5(26%)
Degree		22(43%)	8(38%)	8(42%)
Masters		4(8%)	1(5%)	1(5%)
MHN Experience in years		14.9 (8.1)	15.7 (7.7)	15.8 (6.8)
Time in post	Less than 1 year	5(10%)	3(14%)	2(10%)
	1 – less than 5 years	22(43%)	5(24%)	5(26%)
	5 – less than 10yrs	18(35%)	10(48%)	9(47%)
	10 or more years	6(12%)	3(14%)	3(16%)
Adult nursing qualification		4(8%)	2(9%)	2(10%)
Knowledge MCQ (baseline)		9.3 (2.4) n=51	9.5 (2.9) n=21	10 (2.4) n=19
Attitude PHASe (baseline)		30.4 (5.2) n=38	28.7 (4.7) n=15	28.7 (4.7) n=15
Confidence PHASe (baseline)		14.1 (3.8) n=38	13.2 (3.6) n=15	13.2 (3.6) n=15
Barriers PHASe (baseline)		30.6 (3.2) n=38	29.7 (2.9) n=15	29.7 (2.9) n=15
Attitude towards smoking PHASe (baseline)		19.7 (3.5) n=38	19.3 (3.3) n=15	19.3 (3.3) n=15

Appendix 6

Characteristics of HIP audit samples

Table: Characteristics of audit sample by group

Group		HIP returned	HIP not returned	TAU
Number of patients		n=10	n=10	n=11
		X (%) or mean (sd) unless stated	X (%) or mean (sd) unless stated	X (%) or mean (sd) unless stated
CMHT type	Recovery	6 (60%)	5 (50%)	7 (63.6%)
Months on caseload	median (min,max)	20 (3. 60)	30 (8,96) n=8	26 (1.84) n=10
Primary Diagnosis	Schizophrenia	5 (50%)	5 (50%)	5 (45%)
	Schizoaffective disorder	1 (10%)	1 (10%)	3 (27.3%)
	Bipolar disorder	4 (40%)	4 (40%)	3 (27.3%)
Age in years at consent		52 (10.1)	46.6 (10.7)	45.4 (14.4)
Gender	Male	7 (70%)	6 (60%)	7 (63.6%)
Ethnicity	White British	9 (90%)	10 (100%)	9 (81.8)
Living status	Lives alone	6 (60%)	5 (50%)	6 (54.5%)
Relationship	Single, divorced or widowed	5 (50%)	7 (70%)	6 (54.5%)
Smokes cigarettes		8 (80%)	7 (70%)	5 (45.5%)
Medical Comorbidity Diagnosis^a	None	2 (20%)	1 (10%)	3 (27.3)
	1-4 comorbidities	6 (60%)	8 (80%)	8 (72.7%)
	5 or more	2 (20%)	1 (10%)	0 (0%)
Total number of medications	median (min,max)	4.5 (2, 10)	4.5(2,10)	5 (1.18)
Total number of antipsychotics^a	None	0 (0%)	0 (0%) n=9	2 (18.2%)
	One	7 (70%)	7 (77.8%) n=9	7 (63.6%)
	2 or more	3 (30%)	2 (22.2%) n=9	2 (18.2%)
Prescribed an atypical antipsychotic		10 (100%)	9 (100%) n=9	8 (72.7%)
Prescribed a typical antipsychotic		2 (20%)	0 (0%) n=9	2 (18.2%)
Family History of cardiovascular disease (CVD)		2 (20%)	0 (0%) n=8	5 (45.5%)
Prescribed medicines for CVD^a		5 (50%)	1 (11.1%) n=9	3 (27.2%)

Appendix 7

Unit costs used in economic analysis

Table 1:1 Main unit costs attached to different items of resource use, with associated source.

Item	Estimated unit cost
Mental Health Nurse (per hour of employment)*	£40.00
Mental Health Nurse Trainer (per hour of employment) *	£51.25
Travel (cost per mile)†	£0.45
GP visit (cost per hour of patient contact in surgery)*	£203.00
Community nurse (cost per hour of home visiting) *	£70.00
GP home visit (cost per hour of patient contact out of surgery)*	£258.00
Social worker (cost per hour of patient contact)*	£54.00
Psychiatrist (cost per hour of patient contact)*	£148.00
Counsellor / therapist (per consultation) *	£59.00
Hospital admission (cost per day) #	£338.00
Hospital admission (cost per day) #	£572.00
Day case (Weighted average of all procedures) *	£680.70
A&E visit (not admitted cost)*	£112.00
Paid carers (cost per hour) *	£21.00
Unpaid carer (cost per hour) ‡	£14.76

* Based on Curtis [1]

† Within study assumption

#Taken from the National Schedule of Reference Costs [2]

‡ Based on the Office for National Statistics Annual Survey of Hours and Earnings [3].

1.Curtis, L Unit costs of health and social care 2012. Personal Social Services Research Unit, The University of Kent, 2012.

2.Department of Health Reference Costs 2011-2012. Department of Health, 2012.

3.Office for National Statistics Annual Survey of Hours and Earnings, 2011 Revised Results (SOC 2010). Available at <http://www.ons.gov.uk/ons/rel/ashe/annual-survey-of-hours-and-earnings/2011-revised-results--soc-2010-/index.html> accessed November 4th 2013, 2011.

Appendix 8

Letters of attribution

1. APPENDIX: Contribution to publications cited in support of this thesis

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, 721-727.

I developed and undertook the literature search together with Dr Hardy and under the direct supervision of Dr Deane. The focus of Dr Hardy's doctoral study was the development of physical health care competence in SMI in *primary care* so there was benefit in working together that continues today. Dr Hardy and I wrote the initial draft of the paper together and then liaised by email throughout the review and proof reading stages to publication. Dr Deane and Professor Gray provided supervision throughout this process.

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

The need to develop a pragmatic intervention to support practice change in physical health in SMI was recognised in conversation with Professor Gray and Dr Jones in 2008. Working together and building on existing published evidence, a series of literature reviews performed by all three of us established the variables at risk in SMI, normal and abnormal ranges and recommended action informing the development of the HIP through initial piloting stages to print. I led on the writing stage for this paper that described the process but all three of us contributed, edited and agreed the final version.

2. **White, J.**, Hemmingway, 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

The masterclass project was funded by a grant from the Yorkshire Clinical Skills Network to Mr Hemmingway. I prepared and delivered the masterclass, devised the knowledge questions and collected the data. My Hemmingway and I analysed the data with the support of Dr Stephenson (a statistician). Mr Hemmingway and I then wrote the paper together. All authors contributed to the draft of the manuscript for intellectual content and approved its final version

3. 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.

Frances Shuel [FS] was the senior nurse in Lanarkshire who following HIP training from myself, Professor Gray and Dr Jones obtained governance approval for the service evaluation of the data she had collected. I imported the data from Excel into SPSS, conducted the analysis and wrote the paper, under the supervision of Professor Gray. Dr Jones contributed by editing and providing feedback by email.

4. **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

I imported the (clinical audit) data from Excel into SPSS, conducted the analysis (under supervision of Professor Gray), wrote and submitted the abstract and delivered the presentation.

5. **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.

I wrote this paper under the direct supervision of Professor Gray and with support from the medical statistician, Dr Swift and health economist, Dr Barton, particularly when responding to peer review comments and preparing the analysis section of the final draft. Dr Jones provided some support with responses to questions about the qualitative analysis of the process observation part of the study. The contributions of the funder, sponsor and wider trial steering group were acknowledged. All authors contributed to the draft of the manuscript for intellectual content and approved its final version. The paper was published in *Trials* on 04 July 2011 and quickly achieved high access status. By 25 April 2015 it had been accessed a total of 8766 times.

6. **White, J.** Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomised controlled trial. In submission to *British Journal of Psychiatry*

I together with professor Gray and Dr Jones conceived the study. I wrote the initial draft of the paper with Professor Gray, Miss Lucas and Miss Gough. Dr Swift undertook the intention to treat and per protocol statistical analyses, Dr Barton and Miss Irvine undertook the health economic analyses. Miss Gough and Mr Abotsie undertook the fieldwork. I delivered the HIP

program, as did Professor Gray. I led the project and managed the research team under the supervision of Professor Gray. Miss Lucas and I coordinated the study under the supervision of Professor Gray. All authors contributed to the draft of the manuscript for intellectual content and approved its final submitted version. The role of the funder, NHS sponsor, trial steering group and other fieldworkers in the research team is acknowledged.

7. Hardy, S., **White, J.**, Gray, R. (2015) *The Health Improvement Profile: A manual to promote physical wellbeing in people with severe mental illness*. M&K Publishing. Keswick.

The original manual was written in collaboration with Dr Hardy and under the supervision of Professor Gray. The manual expands on the rationale for each included parameter and the recommended action to take next adapted from the HIP training material. Specific information about how to use the HIP is included. There have been a number of adaptations and translations of the manual for different projects and audiences (e.g. for the primary care HIP, the Cluster RCT, the Humber HIP CQUIN, the Gesundheitsförderungsprofil Psychiatrie and the Hong Kong Chinese HIP). The book represents the most recent version with some additional anatomy and physiology related to comorbidity and publication of the HIP for the first time. Collation of new material and editing of the book was led by Dr Hardy. All authors contributed to the draft of the manuscript for intellectual content and approved its final version.

1.1. Letters of attribution

I have described the contributions of the authors of the publications above. Letters from each of the following authors confirming their role are included at the end of this appendix.

i. Professor Richard Gray

Richard, Dr Jones and I developed the original HIP together. Richard provided me with supervision in the design, execution and writing up of each study.

1. 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, 721-727.
2. White, J., Gray, R. & Jones, M. (2009) The development of the serious mental illness physical Health Improvement Profile. *Journal of Psychiatric and Mental Health Nursing*, 16, 493-498.
3. 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.

4. White, J. (2010). *Evaluation of the serious mental illness Health Improvement Profile [HIP]: The HIP 100*. 16th International Network for Psychiatric Nursing Research
5. (NPNR)Conference: Collaborative research and partnership working 23rd September 2010. Wadham College, Oxford , Royal College of Nursing.
6. 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.
7. Hardy, S., White, J., Gray, R. (2015) *The Health Improvement Profile: A manual to promote physical wellbeing in people with severe mental illness*. M&K Publishing. Keswick.
8. White, J. Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomised controlled trial. In submission to *British Journal of Psychiatry*

ii. Dr Katherine Deane

Katherine provided me with instruction and supervision in carrying out the systematic search. Katherine provided me with supervision and supported my role in the Trial Steering Group, she acted as my primary PhD supervisor from August 2014 when Professor Gray left UEA.

1. 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, 721-727.

iii. Dr Sheila Hardy

Sheila carried out the systematic search with me. We wrote the following publications together.

1. 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, 721-727.
2. Hardy, S., White, J., Gray, R. (2015) *The Health Improvement Profile: A manual to promote physical wellbeing in people with severe mental illness*. M&K Publishing. Keswick.

iv. Mrs Frances Shuel Smillie

Frances implemented the HIP into her work and trained other nurses in the hospital in Lanarkshire where she worked as a senior nurse. She obtained governance permission and collected data for the HIP 31 and HIP 100 service evaluations.

1. 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.

v. Dr Louise Swift

Louise supported the statistical design and carried out the intention to treat and per protocol analyses of the HIP Cluster RCT.

1. 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.
2. White, J. Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomised controlled trial. In submission to *British Journal of Psychiatry*

vi. Dr Gary Barton and Lisa Irvine

Gary supported the health economics design and Gary and Lisa carried out analysis of the HIP Cluster RCT health economic data.

1. 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.
2. White, J. Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomised controlled trial. In submission to *British Journal of Psychiatry*

vii. Miss Joanne Lucas

Joanne was the Trial Coordinator of the HIP Cluster RCT based at UEA. She worked closely with me to undertake the day-to-day organisation of the HIP Cluster RCT in the data collection phase of the study.

1. White, J. Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomised controlled trial. In submission to *British Journal of Psychiatry*

viii. Dr Martin Jones

Martin, Professor Gray and I developed the original HIP together and Martin contributed to the design, execution and analysis of the process observation that followed the HIP Cluster RCT. Martin was a member of the Trial Steering Group in the planning stage.

1. White, J., Gray, R. & Jones, M. (2009) The development of the serious mental illness physical Health Improvement Profile. *Journal of Psychiatric and Mental Health Nursing*, 16, 493-498.
2. 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.
3. 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.

ix. Mr Steve Hemmingway

Steve obtained the grant from the Yorkshire Clinical Skills Network and contributed to the data analysis (with Dr Stephenson, a statistician) and we wrote the paper together.

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

28th April 2015

To Whom It May Concern:

Re: Ms. Jacqueline White

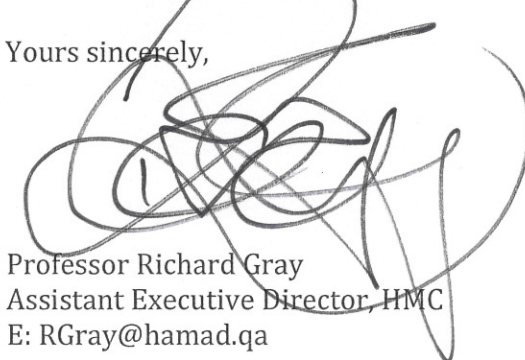
This letter is to confirm that I provided Jacque White with supervision in the design, execution and publication of the studies listed below:

1. 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, 721-727.
2. White, J., Gray, R. & Jones, M. (2009) The development of the serious mental illness physical Health Improvement Profile. *Journal of Psychiatric and Mental Health Nursing*, 16, 493-498.
3. 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.
4. 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.
5. 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.
6. White, J. Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomised controlled trial. In submission to *British Journal of Psychiatry*
7. Hardy, S., White, J., Gray, R. (2015) *The Health Improvement Profile: A manual to promote physical wellbeing in people with severe mental illness*. M&K Publishing. Keswick.

[Type text]

Jacque was the Project Lead on the HIP trial that was funded by the National Institute for Health Research. Dr Martin Jones, and I working with Jacque originally described and developed the HIP.

Yours sincerely,



Professor Richard Gray
Assistant Executive Director, HMC
E: RGray@hamad.qa

[Type text]

Faculty of Medicine and Health Sciences

School of Health Sciences
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University of East Anglia
Norwich Research Park
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Norwich NR4 7UL
United Kingdom

3 May 2015

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Tel: +44 (0) 1603 59 7047
Fax: +44 (0) 1603 59 7019

Dear Jacquie White,

Re: Attribution

This letter is to confirm that I provided instruction and supervision in carrying out the systematic search study below. I additionally supported Jacquie in the design, execution and analysis of the HIP Cluster RCT and process observation, through attendance and contribution to the Trial Steering Group.

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* 16(7): 727.



Dr Katherine Deane BSc PhD,
Senior Lecturer in Research

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Faculty of Medicine and Health Sciences
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University of East Anglia
Colney Lane
Norwich
Norfolk
NR4 7TJ

To whom it may concern

This letter is to confirm that I carried out the systematic search with Jacquie White and we wrote the following publications together:

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, 721-727.

Hardy, S., White, J., Gray, R. (2015) *The Health Improvement Profile: A manual to promote physical wellbeing in people with severe mental illness*. M&K Publishing: Keswick.

Yours faithfully


Dr S A Hardy

Health Improvement Profile Implementation (Lanarkshire)

This letter is to confirm that I implemented the HIP following training from Jacquie White, Professor Gray and Dr Jones into my clinic work and trained other nurses to use the HIP with SMI patients in Lanarkshire. I obtained governance permission and collected data for the following two studies.

Frances Shuel Smillie

A handwritten signature in black ink that reads 'Frances Shuel Smillie'. The signature is written in a cursive style with a large, looped 'O' at the end.

Ward One

Wishaw General

Dr Louise Swift
Chartered Statistician
42 The Green
Surlingham
Norwich
NR147AG
L.swift@uea.ac.uk
Louise@infopragmatica.net

To whom it may concern.

Until November 2014 I worked as a medical statistician at the Norwich Medical School, University of East Anglia. I was a grant holder on a variety of research studies. This letter is to confirm that in this capacity I contributed to the statistical design and performed the intention to treat and per protocol analyses for the following study:

1. 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.
2. White, J. Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomised controlled trial. In submission to *British Journal of Psychiatry*

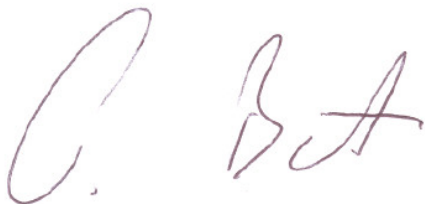
Best wishes

Louise Swift (PhD C.Stat)

To whom it may concern

This letter is to confirm that we contributed the health economics part of the design (GB) and performed analysis of the health economic data (GB, LI) in the following study:

1. 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.
2. White, J. Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomised controlled trial. In submission to *British Journal of Psychiatry*



Garry Barton, Reader in Health Economics

Lisa Irvine, Senior Research Associate in Health Economics

01 May 2015

This letter is to confirm that I acted as the Trial Coordinator of the HIP Cluster RCT based at UEA.

I worked closely with Jacquie White to undertake the day-to-day organisation of the HIP Cluster RCT in the data collection phase of the following study.

1. White, J. Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomised controlled trial. In submission to *British Journal of Psychiatry*



Joanne Lucas

University of Cambridge



University of
South Australia

28 April 2015

To whom it may concern

This letter is to confirm that I along with Jacquie White and Professor Gray developed the original HIP and I contributed to the design, execution and analysis of the process observation that followed the HIP Cluster RCT. Jacquie contributed greatly to the method, data collection, analysis and the synthesis. She played a particularly strong role in assisting to the team to understand some of the barriers the practitioners experienced in the implementation of the Health Improvement Profile.

I supported Jacquie in editing the following publications and agreed the final drafts:

- White, J., Gray, R. & Jones, M. (2009) The development of the serious mental illness Physical Health Improvement Profile. *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., Gray, R. J., Swift, L., Barton, G. R. & Jones, M. (2011) The serious mental illness health improvement profile [HIP]: study protocol for a cluster randomized controlled trial. *Trials*, 12, 167.
- White, J. Lucas, J., Swift, L. Barton, G.R., Gough, H., Irvine, L., Abotsie, G., Jones, M., Gray, R. Effectiveness of health checks to improve the physical health of people with severe mental illness: a single blind cluster randomized controlled trial. In submission to *British Journal of Psychiatry*.

Please get back to me if you require any further information

Yours sincerely,

Dr Martin Jones
Associate Professor
Director
University of South Australia
Department of Rural Health

Department of Rural
Health

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CRICOS Provider Number 00121B

1 May 2015

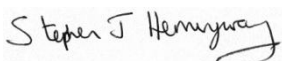
TO WHOM IT MAY CONCERN

Dear Sir/Madam

This letter is to confirm that I obtained the grant from the Yorkshire Clinical Skills Network and I contributed to the design, execution and analysis (with Dr John Stephenson) of the following study. I supported Jacquie in preparing and editing the paper and agreed the final draft:

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

Yours sincerely



Steve Hemingway
Senior Lecturer in Mental Health

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Appendix 9

Publications



Educating healthcare professionals to act on the physical health needs of people with serious mental illness: a systematic search for evidence

S. HARDY¹ RMN RGN BSC (HONS) MSc, J. WHITE^{2,5} RMN BSC (HONS) PG Cert,
K. DEANE³ BSC (HONS) PhD & R. GRAY⁴ RMN PhD

¹Project Lead, PhyHWell Project, Northamptonshire teaching PCT, ²Lecturer/University Teaching Fellow/Faculty Research Fellow, ³Senior Lecturer, ⁴Professor of Research Related to Nursing, Faculty of Health, Nursing and Midwifery, University of East Anglia, Norwich, and ⁵Lecturer/University Teaching Fellow/Faculty Research Fellow, Department of Health and Social Care, University of Hull, Hull, UK

Keywords: dissemination, nurse education, physical health, primary care, secondary care, severe mental illness

Correspondence:

S. Hardy
Francis Crick House
Summerhouse Road
Moulton Park
Northampton NN3 6BF
UK

E-mail: sheila.hardy@uea.ac.uk

Accepted for publication: 16 February 2011

doi: 10.1111/j.1365-2850.2011.01722.x

Accessible summary

- All healthcare professionals caring for people with serious mental illness should be aware of the signs of physical problems and take action to help patients improve their health.
- Our objective is to develop education for healthcare professionals caring for people with serious mental illness to enable them all to offer better physical care.
- We performed a systematic search of the literature and found no papers reporting the outcomes of education with regard to healthcare professionals' knowledge, attitudes and behaviours. The only information reported was the effect of the action taken on patients.
- It is vital that researchers start to publish details of healthcare professional education and their outcomes in physical health research in serious mental illness.

Abstract

Healthcare professionals in primary and secondary care should monitor the physical health of people with serious mental illness, yet in practice this does not appear to be a routine intervention. Our objective is to develop evidence-based training for healthcare professionals to enable them all to offer better physical care to this population. We performed a systematic search with the aim of evaluating the current evidence of the efficacy of education interventions. Search terms covered Severe Mental Illness, Physical Health and Education. The search yielded 147 papers, of which none were eligible for inclusion. 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. It is vital that researchers start to publish details of healthcare professional education and their outcomes in physical health and serious mental illness research.

Introduction

In this paper, the authors of the serious mental illness (SMI) Health Improvement Profile (HIP) and the Health Improve-

ment Profile for Primary Care (HIP-PC) report the lack of evidence for the efficacy of healthcare professional educational outcomes in studies of physical health in SMI. The importance of researchers paying attention to education in



Practice Development

Editor:

Martin Ward

Submissions address:

Cawston Manor, Aylsham Road, Cawston, Norwich,
NR10 4JD, UK

The development of the serious mental illness physical Health Improvement Profile

J. WHITE¹ RN BSC (HONS) PG Cert, R. GRAY² RN PhD &
M. JONES³ RN PhD

¹Lecturer in Mental Health Nursing, University Teaching Fellow, University of Hull, Hull, ²Professor of Research Related to Nursing, University of East Anglia, Norwich, and ³Associate Director of Nursing, Surrey and Borders Partnership NHS Foundation Trust, Surrey, UK

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J. White

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Jacqueline.white@hull.ac.uk

doi: 10.1111/j.1365-2850.2009.01375.x

WHITE J., GRAY R. & JONES M. (2009) *Journal of Psychiatric and Mental Health Nursing* 16, 493–498

The development of the serious mental illness physical Health Improvement Profile

People with serious mental illness (SMI), such as schizophrenia and bipolar disorder, are more likely to suffer from a range of long-term physical conditions including diabetes and cardiovascular disease. Consequently they will die 10–15 years earlier than the general population. Health services have failed to address this major health inequality because of a lack of consensus about the type and frequency of monitoring people with SMI require and a lack of knowledge and skills in the mental health workforce. We developed the SMI physical Health Improvement Profile to help mental health nurses profile the physical health of the SMI patients they work with and direct them towards the evidence base interventions available to address identified health problems.

Keywords: bipolar disorder, HIP, metabolic syndrome, physical health, schizophrenia, serious mental illness

Accepted for publication: 31 October 2008

Background

It is conservatively estimated that people with serious mental illness (SMI) die at least 10–15 years earlier than the general population (Disability Rights Commission 2006). The majority of these premature deaths are not related to suicide but to cardiovascular disease (CVD), the biggest killer in

this population (Newman & Bland 1991, Disability Rights Commission 2006). Rates of CVD are two to three times higher than in the general population (McEvoy *et al.* 2005). This may be because many of the modifiable risk factors associated with CVD, such as smoking, obesity, poor diet, diabetes, hyperlipidaemia and lack of exercise are highly prevalent among people with SMI (Brown *et al.* 2000).

Training Mental Health Nurses to Assess the Physical Health Needs of Mental Health Service Users: A Pre- and Post-test Analysis

Jacqueline White, RMN, BSc(Hons), PGCert, Steve Hemingway, RMN, BA(Hons), MA, PGDE, and John Stephenson, PhD

Jacqueline White, RMN, BSc(Hons), PGCert, is a Senior Lecturer/University Teaching Fellow, Faculty of Health and Social Care, University of Hull, Hull, UK; Steve Hemingway, RMN, BA(Hons), MA, PGDE, is a Senior Lecturer in Mental Health, University of Huddersfield, Huddersfield, UK; and John Stephenson, PhD, is a Senior Lecturer in Health and Biomedical Statistics, School of Human and Health Sciences, University of Huddersfield, Huddersfield, UK.

Search terms:

Bipolar disorder, content analysis, health literacy, mental health nursing, physical health, schizophrenia, serious mental illness (SMI), statistical analysis

Author contact:

jacqueline.white@hull.ac.uk, with a copy to the Editor: gppearson@uchc.edu

Conflict of Interest Statement

The authors report no actual or potential conflicts of interest.

First Received June 19, 2013; Final Revision received August 29, 2013; Accepted for publication October 10, 2013.

doi: 10.1111/ppc.12048

PURPOSE: The aim of this project was to develop, deliver, and evaluate a brief evidenced-based education package to enhance physical health literacy in mental health nurses.

DESIGN AND METHODS: Pre- and post-test survey of knowledge of physical health in serious mental illness, satisfaction with the workshop, and applicability to practice.

FINDINGS: Participants were motivated to attend and complete the questions. There was statistically significant knowledge gain immediately post workshop and participants described satisfaction with the content and a willingness to apply learning from the session to their practice.

PRACTICE IMPLICATIONS: If such workshops are provided as a collaborative and relatively inexpensive way of education, they can contribute to building the capacity of mental health nurses to be literate in physical health interventions.

Improving the physical health of patients with serious mental illness (SMI) such as schizophrenia and bipolar disorder presents a significant challenge to health providers and professionals. Life expectancy is reduced by up to 25 years mainly due to cardiovascular disease with evidence from large cohort studies that this problem has increased since the introduction of new service structures and new medication treatments (Chang et al., 2010; Saha, Chant, & McGrath, 2007; Tiihonen et al., 2009). Cardiovascular disease and diabetes mellitus are two to three times more prevalent in this population (De Hert et al., 2011). Rates of metabolic syndrome (a significant risk factor for the development of diabetes mellitus and cardiovascular disease) as high as 60% have been reported in SMI patients in North America (Kato, Currier, Gómez, Hall, & González-Blanco, 2004). Risk factors for metabolic disease exist in first-episode patients and increase with the duration of illness making the provision of screening and intervention to promote good health of vital importance (De Hert et al., 2006; Mitchell et al., 2012). The prevalence of a whole range of other physical comorbidities is elevated, including respira-

tory disease, bowel cancer, and sexual, eye, and dental health conditions (Stiefel et al., 1990; Cournos, McKinnon, & Sullivan, 2005; Hippisley-Cox, Vinogradova, Coupland, & Parker, 2007; Robson & Gray, 2007).

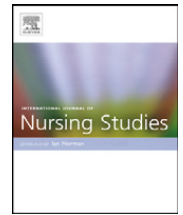
The ability to screen for physiological health conditions is of fundamental importance to mental health nursing practice, yet there is still evidence that such conditions go largely unnoticed, and if identified are often poorly managed (Edward et al., 2012; Phelan, Stradins, & Morrison, 2001). The seriousness of physical symptoms being incorrectly labeled as psychosomatic cannot be underestimated when one considers the number of people with severe and enduring mental illness at risk, termed diagnostic overshadowing (Nocon, 2004). Further studies have demonstrated that individuals who experience mental illness are less likely to be offered or gain access to screening which the general population would expect routinely; for example, cholesterol checks, urine or weight checks, and opportunistic advice regarding smoking cessation (Hardy, Hinks, & Gray, 2013; Mitchell et al., 2012; Phelan et al., 2001). Once a problem is identified,



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Using the serious mental illness health improvement profile [HIP] to identify physical problems in a cohort of community patients: A pragmatic case series evaluation

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ABSTRACT

Background and objectives: The physical health of people with serious mental illness is a cause of growing concern to clinicians. Life expectancy in this population may be reduced by up to 25 years and patients often live with considerable physical morbidity that can dramatically reduce quality of life and contribute to social exclusion. This study sought to determine whether the serious mental illness health improvement profile [HIP], facilitated by mental health nurses [MHNs], has the clinical potential to identify physical morbidity and inform future evidence-based care.

Design: Retrospective documentation audit and qualitative evaluation of patients' and clinicians' views about the use of the HIP in practice.

Setting: A nurse-led outpatient medication management clinic, for community adult patients with serious mental illness in Scotland.

Participants: 31 Community patients with serious mental illness seen in the clinic by 2 MHNs trained to use the HIP. All 31 patients, 9 MHNs, 4 consultant psychiatrists and 12 general practitioners [GPs] (primary care physicians) participated in the qualitative evaluation.

Methods: A retrospective documentation audit of case notes for all patients where the HIP had been implemented. Semi-structured interviews with patients and their secondary care clinicians. Postal survey of GPs.

Results: 189 Physical health issues were identified (mean 6.1 per patient). Items most frequently flagged 'red', 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 ($n = 13$). Some rates of physical health problems observed were broadly similar to those reported in studies of patients receiving antipsychotics in primary care but much lower than those reported in epidemiological studies. Individualised care was planned and delivered with each patient based on the profile. 28 discreet interventions that included providing advice, promoting health behavioural change, performing an electrocardiogram and making a referral to professional colleagues were used. Qualitative feedback was positive. Our observations support the use of the HIP in clinical settings to enhance mental health nursing practice; however, we strongly recommend that training is required to support the use of the HIP.

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STUDY PROTOCOL

Open Access

The serious mental illness health improvement profile [HIP]: study protocol for a cluster randomised controlled trial

Jacquie White^{1,2*}, Richard J Gray³, Louise Swift³, Garry R Barton² and Martin Jones⁴

Abstract

Background: The serious mental illness Health Improvement Profile [HIP] is a brief pragmatic tool, which enables mental health nurses to work together with patients to screen physical health and take evidence-based action when variables are identified to be at risk. Piloting has demonstrated clinical utility and acceptability.

Methods/Design: A single blind parallel group cluster randomised controlled trial with secondary economic analysis and process observation. Unit of randomisation: mental health nurses [MHNs] working in adult community mental health teams across two NHS Trusts. Subjects: Patients over 18 years with a diagnosis of schizophrenia, schizoaffective or bipolar disorder on the caseload of participating MHNs. Primary objective: To determine the effects of the HIP programme on patients' physical wellbeing assessed by the physical component score of the Medical Outcome Study (MOS) 36 Item Short Form Health Survey version 2 [SF-36v2]. Secondary objectives: To determine the effects of the HIP programme on: cost effectiveness, mental wellbeing, cardiovascular risk, physical health care attitudes and knowledge of MHNs and to determine the acceptability of the HIP Programme in the NHS. Consented nurses (and patients) will be randomised to receive the HIP Programme or treatment as usual. Outcomes will be measured at baseline and 12 months with a process observation after 12 months to include evaluation of patients' and professionals' experience and observation of any effect on care plans and primary-secondary care interface communication. Outcomes will be analysed on an intention-to-treat (ITT) basis.

Discussion: The results of the trial and process observation will provide information about the effectiveness of the HIP Programme in supporting MHNs to address physical comorbidity in serious mental illness. Given the current unacceptable prevalence of physical comorbidity and mortality in the serious mental illness population, it is hoped the HIP trial will provide a timely contribution to evidence on organisation and delivery of care for patients, clinicians and policy makers.

Trial Registration: ISRCTN: ISRCTN41137900

Background

Serious mental illness and physical comorbidity

Improving the physical health of people with serious mental illness [SMI] (people with a diagnosis of schizophrenia, schizoaffective or bipolar disorder) is an important public health challenge [1,2]. Comorbid physical illness dramatically reduces life expectancy; epidemiological studies report 20-25 years earlier mortality in schizophrenia and 10-15 years in bipolar disorder [3,4].

Metabolic disorders such as diabetes, hyperlipidemia and hypertension are highly prevalent, exceeding 50% in some studies [5]. Cardiovascular disease [CVD] is the most common cause of early mortality; lifestyle and risk factors are common and may be exacerbated by antipsychotic medication [6,7]. Rates of respiratory disease, HIV and some cancers are higher than expected [8]. Poor eye, foot, bowel and dental health, sleep problems and sexual dissatisfaction contribute to social exclusion [9-11].

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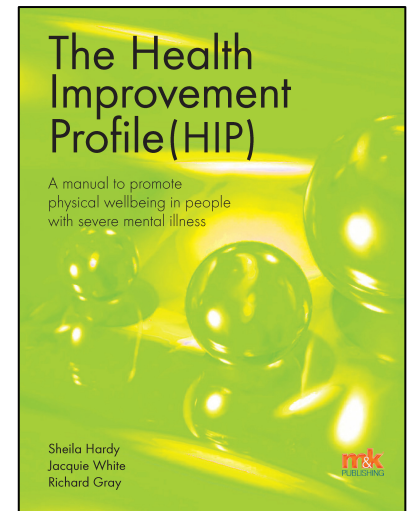
The Health Improvement Profile:

A manual to promote physical wellbeing in people with severe mental illness

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Dr Sheila Hardy, Senior Research Fellow, Northamptonshire Healthcare NHS Foundation Trust; **Jacquie White**, Deputy Head, Department of Psychological Health and Wellbeing, University of Hull; **Professor Richard J Gray**, Leads a multidisciplinary Health Services Research group in Doha, Qatar



This practical guide, written by experts in mental health nursing, is designed to support healthcare practitioners in checking the physical health of people with severe mental illness (SMI).

As life expectancy is reduced by 12 to 19 years in people with SMI, this patient group should receive a physical health check at least once a year. Yet many mental health practitioners have not been trained to assess their physical health needs, and even when such training is offered it may be difficult to access it because of clinical workloads.

The Health Improvement Profile (HIP) provides an efficient, effective, evidence-based physical health check tool specifically designed to be used when assessing people with SMI. It supports practitioners in identifying physical health problems and guides them towards evidence-based interventions to address common health issues affecting people with SMI, ranging from cardiovascular disease to lifestyle factors such as diet, alcohol and smoking.

Contents include:

- Introduction
- What is severe mental illness?
- What treatments are used in severe mental illness?
- Systems of the body that are commonly affected in people with severe mental illness
- Common physical comorbidities in people with severe mental illness
- Cardiovascular disease in people with severe mental illness
- Problematic behaviours affecting health in people with severe mental illness
- How to use the Health Improvement Profile (physical health check tool)
- Changing behaviour to improve health
- Appendix 1: Health Improvement Profile (HIP) – Female
- Appendix 2: Health Improvement Profile (HIP) – Male

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