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Recovery through healthy living in acute psychiatric setting

Submission date	Recruitment status	[ ] Prospectively registered
31/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/07/2016	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Anca Alba

Contact details
Health Sciences Research Institute
Warwick Medical School
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5834

Study information

Scientific Title
Pilot study to enhance recovery through physical activity and healthy lifestyles in an acute psychiatric day hospital setting

Study objectives
Individuals with serious mental disorders die up to 30 years earlier than the general population, mostly from cardiovascular causes. Explanations include obesity, diabetes, hypertension, smoking, poor diet and sedentary lifestyle. Diabetes is three times more common in schizophrenia than in the general population, and twice as common in depression. Despite calls for urgent action, services to address this problem are rare. This is partly due to the dearth of evidence to guide implementation.

Trials in diabetes and hypertension show that that increasing physical activity can be effective and sustainable, but this requires motivational support. There have been a few lifestyle change interventions among people with serious mental illness, but none has been fully evaluated to date. If effective, acceptable and sustainable, an intervention that improved the physical health of people with serious mental illness could transform the prognosis of these disorders. The payoffs in increased life expectancy and improved quality of life are enormous.

The proposed study aims to develop and extend a newly established healthy living initiative designed to improve the physical health of individuals with serious mental illness, in preparation for a Phase III trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Warwickshire Research Ethics Committee, 26/02/2009, ref: 09/H1211/2

Study design
Non-randomised multicentre interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: All Diagnoses; Disease: Not Applicable

Interventions
All service users will be invited to participate in the study on admission and those who agree and consent will undergo a physical health and lifestyle assessment. In addition to cardiovascular and metabolic risk factors, general fitness and any musculoskeletal problems will be assessed by the project Physiotherapist. The latter will also be responsible for completing individually-tailored Healthy Lifestyle care plans addressing physical activity, weight, diet and smoking as soon as practicable after admission. Each participant will be given (and allowed to keep) an inexpensive pedometer to encourage self-monitoring of physical activity. Participants will be offered regular, individual monthly review of these lifestyle care plans, and this will be reinforced in weekly meetings with key workers and at fortnightly multidisciplinary clinical review meetings. Caroline Morgan, a senior RMN at Willow View, initiated the service and continues to oversee its delivery. She will continue to coordinate and champion the Healthy Lifestyles Programme within the Day Hospital with support from the project Physiotherapist.

As part of lifestyle care plans, participants will be encouraged to take part in a range of activities, according to physical and mental health and personal preferences. Most activities take place off-site, typically within local authority leisure facilities. Participation in activities outside of mental health settings reduces perceived stigma, increases the range of available activities and encourages maintenance beyond discharge from Willow View. Attendees can choose from aerobic step class, circuit training, swimming, badminton, cycling, individual or group walking, and yoga. We will also look to increase the range of activity options - like 5-a-side football, gardening clubs and Tai Chi - in collaboration with other stakeholders. Widening the repertoire of available activities through local partnerships will be a key role of the project Physiotherapist. Where appropriate, staff will accompany individuals or groups of service users to encourage participation.

Healthy lifestyle group:
All service users at Willow View are encouraged to attend a weekly Healthy Lifestyles group. This open group meets for 1.5 hours each week, with a rolling programme covering all aspects of lifestyle such as diet (including budgeting, cooking and daily fruit and vegetable consumption, weight and reasons for and alternatives to overeating. Once every 6 - 8 weeks an outside speaker attends, including a community dietician, a smoking cessation counsellor, and colleagues from the community alcohol service. Regular physical activity is strongly encouraged, with timetabled sessions for this. This integrated 'healthy lifestyle' ethos permeates the service; for example, the budgeting and cooking skills group designed to enhance skills of daily living reinforces the health eating message.

Intervention Type
Behavioural

Primary outcome measure
Height, weight, body mass index (BMI), and central (visceral) obesity using waist circumference, measured at baseline, 3 months and 6 months follow-up.

Secondary outcome measures
Clinical and functional outcomes will be assessed using the Core Assessment and Outcomes Package, measured at baseline, 3 months and 6 months follow-up.

Overall study start date
01/01/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Individuals aged 18 - 65 years (either sex)
2. Diagnosis of schizophrenia, bipolar disorder, depression, anxiety disorder (including OCD) or personality disorder

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100

Key exclusion criteria
1. Serious cardiovascular pathology
2. Uncontrolled hypertension
3. Liver disease
4. Renal failure

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Warwick Medical School
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
Gibbet Hill Road
Coventry
England
United Kingdom
CV4 7AL
-
P.A.Hedges@warwick.ac.uk

Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration