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Structured lifestyle education for people wIth schizophrenia

Submission date	Recruitment status	[X] Prospectively registered
20/03/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/03/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/11/2019	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

There is an urgent need to develop ways to help people with schizophrenia and other severe mental illnesses (SMI) to manage their weight. Obesity and overweight occur 23 times more commonly among people with schizophrenia. As well as increasing the risk of physical health problems such as diabetes and heart disease, weight gain may be a reason that stops people from taking their medication. This can make their mental health worse. There is evidence to suggest that people with schizophrenia can change their diet and exercise habits, with appropriate support, in the short term. Research is needed to see whether lifestyle interventions are effective in promoting further weight loss in the longer term for people with SMIs. This aim of this study is to develop a lifestyle education programme that meets the needs of people with SMI and first episode psychosis. We will adapt the programme from a successful education programme called DESMOND, which was developed for people with diabetes or at risk of diabetes.

Who can participate?

We aim to recruit around 400 people with schizophrenia (including first episode psychosis) from 10 Mental Health Trusts in the UK.

What does the study involve?

In the first part of the study trained educators will deliver a test programme to patients in three cycles. Feedback from each cycle will be used to improve the programme. In the second part of the study participants will be randomly allocated to one of two groups. One group will continue to receive their usual health and social care. The other group will receive their usual health and social care and also the programme developed during the first part of the study. This is likely to be delivered over several weekly sessions followed by 'booster' sessions every 3 months. It is important to find out if people with schizophrenia can change their lifestyle and lose weight as a result of the education programme. We will measure body weight during the trial and measure other potential health benefits from changes in diet and physical activity. We will also see whether the programme is acceptable to people with SMI, their carers and health care professionals.

What are the possible benefits and risks of participating?
Previous research studies suggest that lifestyle education programmes can lead to reductions in body weight and diabetes. People often feel better as a result of the increase in exercise and healthier diet. The study is unlikely to cause harm but it is possible that participants may injure themselves through doing physical activity they are not used to. Although no adverse effects are anticipated, the education programme may not help people to lose weight or prevent weight gain.

Where is the study run from?
This study is sponsored by Sheffield Health and Social Care NHS Foundation Trust and managed by Sheffield Clinical Trials Research Unit (CTRU), The University of Sheffield.

When is the study starting and how long is it expected to run for?
Recruitment is due to start in December 2014 and will run until March 2016. All participants can expect to be involved in the study for about 12 months. Follow-up is expected to finish in March 2017.

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Rebecca Gossage-Worrall
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Study website
http://www.shef.ac.uk/scharr/sections/dts/ctru/stepwise

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/28/05; 16040

Study information

Scientific Title
STEPWISE: a multi-centre randomised controlled trial assessing STructured lifestyle Education for People WIth SchizophrEnia (including first episode psychosis) to reduce weight gain of patients prescribed antipsychotic medication

Acronym
STEPWISE

Study objectives
There are two stages involved in STEPWISE:
1. The intervention development study (IDS) will adapt the NICE approved education programme DESMOND™, to meet the needs of people with schizophrenia.
2. A multicentre open-labelled individually randomised (parallel group) controlled trial of a group lifestyle education programme in people with schizophrenia including those with first episode psychosis.

The primary objective of the trial is to evaluate the effectiveness of structured lifestyle education on reduction of weight gain for people with schizophrenia and first episode psychosis.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/122805
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0019/115561/PRO-12-28-05.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Yorkshire and the Humber - South Yorkshire, 04/02/2014, ref: 14/YH/0019

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Schizophrenia; Disease: Schizophrenia

Interventions
NICE recommended usual care: An annual physical health review as per the NICE guidelines. Verbal & printed advice on the risk of weight gain & lifestyle advice, including information about diet, exercise, smoking & alcohol use.

Structured lifestyle education: An adapted DESMOND programme delivered to a group of approximately 6-8 people in 4 weekly sessions lasting 1.5 hours, by two trained facilitators, with modules (such as, the patient story, physical activity, and diet) designed to target perceptions and knowledge of risk status and chronic disease, self-efficacy and response-efficacy beliefs around health behaviour. Support contract and booster sessions provided by facilitators.

Follow Up Length: 12 month(s)
Study Entry: Single Randomisation only

Intervention Type
Behavioural

Primary outcome measure
Weight (kg) at 12 months after randomisation; Timepoint(s): 12 months

Secondary outcome measures
1. Adapted Brief Illness Perception Questionnaire; Timepoint(s): 3 and 12 months
2. Adapted Dietary Instrument for Nutrition Education; Timepoint(s): 3 and 12 months
3. Adverse events; Timepoint(s): 3 and 12 months
4. Blood pressure; Timepoint(s): 3 and 12 months
5. Body Mass Index; Timepoint(s): 3 and 12 months
6. Brief Psychiatric Rating Scale; Timepoint(s): 3 and 12 months
7. Changes in medication; Timepoint(s): 3 and 12 months
8. Client Service Receipt Inventory; Timepoint(s): 3 and 12 months
9. EQ-5D 5L; Timepoint(s): 3 and 12 months
10. Fasting glucose, lipid profile and glycated haemoglobin (HbA1c); Timepoint(s): 12 months
11. Patient Health Questionnaire 9 (PHQ-9); Timepoint(s): 3 and 12 months
12. RAND SF36; Timepoint(s): 3 and 12 months
13. Smoking status; Timepoint(s): 3 and 12 months
14. Waist circumference; Timepoint(s): 3 and 12 months
15. Weight; the proportion who maintained or reduced weight; percentage change in weight; Timepoint(s): 3 and 12 months
16. Wrist worn accelerometry (7-day GeneActiv); Timepoint(s): 3 and 12 months

Overall study start date
01/12/2014

Completion date
06/04/2017

Eligibility

Key inclusion criteria
1. Age ≥ 18 years old. There is no upper age limit.
2. Clinical diagnosis of schizophrenia (defined by Internal Classification of Diseases (ICD-10) codes F20 - Schizophrenia and F25 - Schizoaffective disorders)) including first episode psychosis using case note review. There is no limit on the duration of illness
3. Patients must have been treated with an antipsychotic. For those with established schizophrenia, the treatment duration should be at least 1 month prior to the start of the trial.
4. Ability to give written informed consent
5. Ability and willingness to attend and participate in a group education programme
6. Ability to speak and read English
7. Body mass index 25 kg/m2 or concerned about weight gain since treatment initiation. For patients from South Asian and other Black and Minority Ethnic backgrounds, the BMI threshold will be reduced to 23 kg/m2.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 412; UK Sample Size: 412; Description: A sample size of 206 patients for each trial arm (412 in total).

Key exclusion criteria
1. Physical illnesses that could seriously reduce their life expectancy or ability to participate in the trial
2. A co-existing physical health problem that would, in the opinion of the medical investigators, independently impact on metabolic measures.
3. Mental illnesses that could seriously reduce their ability to participant in the trial
4. Current pregnancy, plus mothers less than 6 months post-partum. Conditions associated with significant weight gain e.g. Cushing's syndrome
5. Significant alcohol or substance misuse
6. A diagnosis or tentative diagnosis of psychotic depression or mania
7. A primary diagnosis of learning disability
8. Already engaged in a systematic weight management programme.

Date of first enrolment
01/12/2014

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Health Services Research, School of Health & related Research (ScHARR)
Sheffield
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S1 4DA

Sponsor information

Organisation
Sheffield Health and Social Care NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/05cn4v910

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in late 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/09/2016		Yes	No
Results article	results	01/11/2018		Yes	No
Results article	results	01/02/2019		Yes	No
Other publications	process evaluation	13/11/2019	15/11/2019	Yes	No
HRA research summary			28/06/2023	No	No