

Efficacy of the BELA weight management programme to prevent increase of weight in schizophrenic patients treated with olanzapin (BELA = movement - nutrition - learning - accepting)

Submission date 18/04/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 30/05/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 30/05/2008	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
GM2_2007

Study information

Scientific Title

Acronym

BELA

Study objectives

To assess the efficacy of preventative effects of the BELA programme on weight and metabolic parameters in schizophrenic patients treated with olanzapin.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee of Medical Faculty of Heinrich-Heine University. Date of approval: 07/02/2008 (ref: MC-LKP-249)
2. Federal Institute for Drugs and Medical Devices (BfArM). Date of approval: 06/12/2007 (ref: 4033665)

Primary study design

Interventional

Study design

Phase IV, multi-centre, open, two-arm randomised controlled trial.

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

This trial is taking place at four sites (Düsseldorf, Bochum, Krefeld, Dortmund). Participants will be randomly allocated to the two arms in equal numbers:

Intervention group: Standard therapy + BELA weight management programme

Control group: Standard therapy only

The psychoeducation programme BELA has been developed at the beginning of 2005 for psychiatric patients. The contents of the psychoeducation are based on the knowledge that better nutrition and regular exercise may stabilise the individual course of disease, the detection of bad habits and the implementation, practice and stabilisation of individual, appropriate habits. As far as methods are concerned, these are simple pedagogic and informational modules (adapted to the type of patients) and which result in experiment-orientated, practical exercises. The BELA concept is geared to small groups (6 - 10 patients) in order to, for example, allow the planning, shopping, cooking of a meal. Over a period of 10 weeks there are group meetings, each 60 minutes, with knowledge transfer of nutrition and exercising.

Content of patient-education:

1. Aim of the course
2. Energy and calories
3. Types of provisions
4. Major nutrients
5. Pathology
6. Planning the day
7. Fats
8. Recipes
9. Cooking with vegetables, etc. (practical)
10. Relevance of exercises

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Olanzapin

Primary outcome(s)

Weight changes in kg, measured at week 1 and week 10.

Key secondary outcome(s)

1. Influence of the intervention on further risk factors, assessed by the following:
 - 1.2. Cholesterol at Week 2, 1, 5, 10, 14 and 18
 - 1.3. low density lipoprotein (LDL) at Week 2, 1, 5, 10, 14 and 18
 - 1.4. Triglyzeride at Week 2, 1, 5, 10, 14 and 18
 - 1.5. high density lipoprotein(HDL) at Week 2, 1, 5, 10, 14 and 18
 - 1.6. HbA1c at Week 1, 10 and 18
 - 1.7. Glucose at Week 2, 1, 5, 10, 14 and 18
 - 1.8. Blood-pressure at Week 2, 1, 5, 10, 14 and 18
 - 1.9. Abdominal girth at Week 2, 1, 5, 10, 14 and 18
 - 1.10. Body mass index (BMI) at Week 2, 1, 5, 10, 14 and 18
2. Identification of indicators with regard to weight increase and the response on weight management by acquisition of the following parameters:
 - 2.1. Age, sex, initial weight 2 weeks prior to intervention
 - 2.2. Psycho-pathological rating-scales:
 - a. Positive and Negative Syndrome Scale (PANSS) 2 weeks before intervention and then at weeks 1, 5, 10, 14 and 18
 - b. Personal social achievement rating scale (persönliche soziale Leistungskala [PSL]) at weeks 1, 10 and 18
 - c. 36-item Short Form health survey (SF-36) at weeks 1, 10 and 18
 - d. Body image assessment questionnaire (Fragebogen zur Beurteilung des eigenen Körpers [FBek]) at weeks 1, 10 and 18
 - e. Type D Personality Scale (DS14) 2 weeks prior to intervention
 - f. Global Assessment of Functioning (GAF) at weeks 1, 10 and 18
 - 2.3. Medical genetics: Polymorphism for weight increase, assessed at week 1
 - 2.4. Lipometabolism: Participating hormones and interleukine: leptin, ghrelin, adiponektin, cortisone, retinol binding protein 4 (RBP-4), IL-6, TNF-alpha. These will be assessed at weeks 1,

10 and 18

3. Increase of weight (in kg) of the intervention group in comparison to the control group at the end of the follow-up phase (Week 1 [before the intervention phase] vs Week 18 [after the follow-up phase])

Completion date

15/11/2010

Eligibility

Key inclusion criteria

1. Both males and females
2. Age 18 - 65 years
3. Criteria of the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM IV) for schizophrenia or schizoaffective psychosis
4. Written informed consent
5. Capability of signing informed consent
6. Olanzapin medication

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Serious somatic diseases
2. Changes in weight due to somatic diseases
3. Pregnancy or lactation
4. Increase of weight of more than 3 kg over the last 3 months before start of treatment with olanzapin
5. Co-medication with a weight-reducing potential
6. Participation in another interventional trial which could interfere with this trial

Date of first enrolment

03/04/2008

Date of final enrolment

15/11/2010

Locations

Countries of recruitment

Germany

Study participating centre

Clinic and Polyclinic for Psychiatry and Psychotherapy

Düsseldorf

Germany

40629

Sponsor information

Organisation

Heinrich-Heine University (Germany)

ROR

<https://ror.org/024z2rq82>

Funder(s)

Funder type

University/education

Funder Name

Heinrich-Heine University (Germany)

Funder Name

Lilly GmbH (Germany)

Funder Name

Note: This is an investigator initiated trial.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration