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An attempt to improve physical and psychological health through study circles among persons with psychiatric disabilities

Submission date	Recruitment status	[ ] Prospectively registered
28/08/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/07/2019	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VLL 1561:58-2004

Study information

Scientific Title
A cluster randomised controlled life style intervention for persons with psychiatric disabilities

Acronym
CRCLI

Study objectives
Risk factors for somatic diseases as well as indicators for quality of life and sense of coherence will significantly change in a positive direction as a result of the intervention as compared to controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board at Umeå University. Date of approval: 11/01/2005 (ref: nr 04-177M)

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Psychiatric disability and co-morbidity

Interventions
The age range of the participants was 23-71 years.

The intervention groups were offered a programme for healthy living in a form of a study circle developed by the Workers Educational Association (ABF). The study material has been used for the general population as well as for groups of persons with functional impairments. Each intervention group circle comprised of 5 to 12 residents and staff members with the same leader. Each study circle met twice a week for two hours for the duration of the 12 month programme; one session focused on the cooking of good nourishing food and the other on physical activity. The sessions took place in the staff flat, where most of the cooking was carried

out. A balanced diet chart, the importance of main meals and snacks, fruits, vitamins, diet fibres, sugar and fat were topics for the discussions. The lessons were mainly practical with a short theoretical content. While buying ingredients, baking bread or preparing a meal, the members were encouraged to read and discuss the declaration of contents of the various foodstuffs and how to make healthy and economical choices. The lessons required an active participation in activities regarding planning, food preparation and washing up the dishes.

The physical activity sessions gave the participants the opportunity to try various types of sports and training. There was a mixture of fitness training, team games, individual games and open-air activities for example walks, badminton, bowling, table tennis, indoor bandy, swimming, working-out, bicycle excursions, jig fishing, and gathering mushrooms. These sessions also contained a short theoretical content such as the nature of the human body and the necessity to be active to maintain its functions, avoiding injuries related to training, motivation, goals, but also information about tobacco, alcohol and drugs. The staff participated in all activities on basically the same conditions as the residents, doing the same tests, answering the same questionnaires and participating in the study circle, but at the same time supporting the leader and the residents.

The participants in the control groups were offered an aesthetic study circle in five groups entitled "Colour and Shape". The number of residents and staff varied between five and nine and they met once a week for two hours mainly at the staff flat, where some of the activities took place. The participants had the opportunity to learn and practice various kinds of artistic techniques e.g., sketching, charcoal drawing, pencil drawing, oils, batik and collage. The access to a pottery gave the opportunity to try different techniques with clay and the participants also went to art exhibitions and were encouraged to look at art and discuss it. Total duration of the aesthetic study programme: 12 month.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following will be assessed at baseline and follow-up after 12 month of intervention:
1. Changes in HeartScore®
2. Body mass index (BMI)
3. Criteria for metabolic syndrome: Hba1c, P-gluc, P-ins, lipids, heart rate, blood pressure, weight, height, waist circumference, incremental shuttle walking test (ISWT)
4. Sense of Coherence Scale (SOC)
5. Global Assessment of Functioning Scale (GAFS)
6. Manchester Short Assessment of Quality of Life (MANSA)

Secondary outcome measures
The following will be assessed at baseline and follow-up after 12 month of intervention:
1. Changes in physical activity: the participants used a pedometer SILVA™ Pedometer Plus attached to their hip ten hours per day (between 9 am to 7 pm) during one week at baseline and follow-up.
2. Symptom Checklist-90-R (SCL-90-R)
3. 36-item Short Form Health Survey (SF-36)

Overall study start date
15/05/2005

Completion date
15/05/2006

Eligibility

Key inclusion criteria
1. Both males and females
2. Persons with psychiatric disabilities (diagnoses of schizophrenia, bipolar disorder, severe personality disorders) recieving social support in supported housing facilities and their staff who consented to take part in the study
3. No age limit (However, the supported housing are available for persons with psychiatric disability over 18 years or older)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
82 in total (41 staff members)

Total final enrolment
82

Key exclusion criteria
Those that did not accept to take part in the study.

Date of first enrolment
15/05/2005

Date of final enrolment
15/05/2006

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Clinical Sciences/Psychiatry
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Sponsor information

Organisation
County Council of Västerbotten (Sweden)

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Sponsor type
Government

Website
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ROR
https://ror.org/04xvhsp09

Funder(s)

Funder type
Government

Funder Name
County Council of Västerbotten (Sweden)

Funder Name
The Vårdal Institute: The Swedish Institute for Health Sciences (Sweden)

Funder Name

The Swedish Council for Working Life and Social Research (FAS) (Sweden)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2008	03/07/2019	Yes	No