

Health promotion in community residences

Submission date 24/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/03/2011	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HSN 0802-0339

Study information

Scientific Title

Health promotion in community residences for people with intellectual disabilities: A randomised controlled trial

Study objectives

The overall aim is to develop and evaluate the effects of a health education programme directed at both staff and residents in community residences for people with intellectual disabilities. Specific objectives are to study improvements in work routines and environment and to study individual effects on dietary and physical activity habits, BMI, waist circumference and quality of life due to the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Regional Ethical Review Board in Stockholm on the 17th of September 2009 (ref: 2009/1332)

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Prevention of obesity and chronic diseases related to diet and physical activity among adult people with intellectual disabilities

Interventions

32 community residences are selected in Stockholm county and randomised to intervention (n=16) and control (n=16) residences. The intervention group takes part in a health programme including three main components, which will be implemented during 12 months:

1. A health education activity including diet and physical activity targeting residents in community residences. The activity consists of ten sessions which will be carried out in the residences by an external educator.
2. A health ambassador will be appointed among staff members in each residence. The health ambassador will be responsible for health issues and will receive coaching by the project team.
3. The staff in every community residence will come together in 10 sessions to discuss health

issues. A discussion leader will be appointed and the group will meet to discuss ten different themes on the basis of a programme material developed specifically for this project.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Physical activity will be assessed by pedometry for seven consecutive days. The data will be collected before and after intervention. Parametric and non-parametric tests will be used to compare groups at baseline. Multilevel analysis will be used to evaluate the effects of the intervention outcomes.

Two levels are defined in the analysis:

1. resident
2. residential setting

Linear and logistic regression models will be used to study the effects on the outcome variables.

Secondary outcome measures

1. BMI and waist circumference will be measured by the research team
2. Dietary habits will be assessed by use of digital photography taken by residents for three days
3. Quality of life will be assessed by a structured interview

The analysis will be carried out as for the primary outcome.

Overall study start date

01/08/2009

Completion date

31/12/2011

Eligibility**Key inclusion criteria**

Community residences for adult people with mild or moderate intellectual disabilities, in Stockholm County. A minimum of three residents in each residence who agree to participate.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

160

Key exclusion criteria

1. Community residences for adult people with severe intellectual disabilities
2. People with intellectual disabilities living on their own

Date of first enrolment

01/08/2009

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Sweden

Study participating centre

Karolinska Institutet

Stockholm

Sweden

104 62

Sponsor information

Organisation

Health Care Board and Management (Hälsö- och sjukvårdsnämndens förvaltning) (Sweden)

Sponsor details

Folkhälsoanslaget

Box 6909

Stockholm

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Sponsor type

Government

ROR

<https://ror.org/04d5f4w73>

Funder(s)

Funder type

Government

Funder Name

Stockholm County Council (Folkhälsoanslaget) (Sweden)

Alternative Name(s)

Stockholm County Council

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

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?
Protocol article	protocol	13/12/2010		Yes	No