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Promotion of physical activity in obese women through walking and bicycling

Submission date	Recruitment status	[_] Prospectively registered
10/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/12/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Bicycling as a complement to walking for promoting physical activity in abdominally obese, middle-aged women: a randomised, controlled trial

Acronym
Stockholm Bicycling Trial (SBT)

Study objectives
We hypothesised that bicycling treatment success would be more common in the intervention group than the control group, whereas no such difference would be found for walking.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional research ethics committee in Stockholm (located within the Karolinska Institute), Sweden. Approval was granted on 1 February 2005 (ref: 04-963/2)

Study design
Randomised, controlled, single-blind, single-centre trial with intention to treat analysis

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Abdominal obesity

Interventions
Participants were allocated to the two programmes in equal numbers:
Intervention programme: Bicycling and walking + physician visits and group sessions
Control programme: Walking + group sessions

The theoretical framework of behaviour change for both groups was the Transtheoretical model. We specifically focused on three processes of change:
1. Raising awareness (e.g., increased understanding of the need for intervention, or the identification of day-to-day variations in activity)
2. Countering (swapping an unhealthy behaviour for a healthy behaviour e.g., bicycling as opposed to driving to and from work)
3. Helping relationships (support from family and friends, fellow outpatients and therapists, walking groups at work, or encouragement from a spouse)

The control group received a low-intensity, pedometer-driven walking intervention. After baseline, the participants were encouraged to gradually increase their daily amount of walking up to 5,000 steps/day above baseline. However, we also encouraged other forms of exercise, if that was their preference (swimming, aerobics, gardening, etc.). Pedometer interaction (using it to count steps, to act as a motivator, to inform about how to reach their targets, etc.) was consistently encouraged. Participants who recorded low levels of daily walking at baseline (e.g., 3,000-4,000 steps/day) were told to gradually increase their weekly walking averages in increments of 2,000 steps/day (for example, going from a weekly average of 4,000 steps/day to 6,000 steps/day), and if feasible reach 10,000 steps/day towards the end of the follow-up. We also communicated the general recommendation to walk 10,000 steps per day, as a suitable goal. Walking recommendations were provided during the group counselling sessions in the control group and during the individual physician visits in the intervention group.

The group sessions (at 0 and 6 months) emphasised the importance of building routines for physical activity in everyday life, primarily by changing mode of transport to and from work (e.g., using public transport instead of driving, walking instead of taking the bus, getting off at an earlier stop).

Instructions aimed to achieve a balance between meaningful behavior change and increased risk of relapse and injuries. The women were encouraged to work out their own physical activity plan, and eventually become self-sufficient walkers. During the group sessions we promoted autonomy by reinforcing positive aspects, boosting self-efficacy, and enhancing their incentive to be physically active (explaining health gains associated with increased physical activity).

The intervention group received, in addition to the standard care package, three added components:
1. Three individual 30 minute sessions with a physician experienced in behavior change theory and practice at 0, 6, and 12 months, where they were given physical activity prescriptions (specifically developed by Swedish authorities to promote physical activity within the national health system, "FYSS"). The prescriptions focused on increased bicycling and walking, mainly between work and home.
2. A new ladies model bicycle (Crescent CTC 670, 2005 model, Sweden) complete with 7 gears, basket, trip meter, foot brake and helmet (retail cost SEK6,000, approximately $900) with free of charge bicycle service
3. Two 2-hour group counselling sessions during the bicycling season (at 2 and 14 months)

Duration of intervention: 18 months

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Physical activity:
1. Bicycling (proportion reaching the treatment success cut-off of 2 km/day) measured with a trip meter for 7 consecutive days at the following time points: 0, 2, 4, 6, 8, 10, 12, 14, 16 and 18 months.
2. Walking (proportion reaching the treatment success cut-off of 10,000 steps/day) measured with a Yamax SW-200 pedometer for 7 consecutive days at the following time points: 0, 2, 4, 6, 8, 10, 12, 14, 16 and 18 months.

Transportation:
3. Use of cars in the transport to and from work measured with a 7 day diary at the following time points: 0, 2, 4, 6, 8, 10, 12, 14, 16 and 18 months.
4. Use of public transport for commuting to and from work measured with a 7 day diary at the following time points: 0, 2, 4, 6, 8, 10, 12, 14, 16 and 18 months.
5. Bicycling for commuting to and from work measured with a 7 day diary at the following time points: 0, 2, 4, 6, 8, 10, 12, 14, 16 and 18 months.
6. Walking for commuting to and from work measured with a 7 day diary at the following time points: 0, 2, 4, 6, 8, 10, 12, 14, 16 and 18 months.

Key secondary outcome(s))

1. Body composition: Dual energy X-ray Absorptiometry (DXA) measured at 0, 6 and 18 months
2. Metabolic risk factors for cardiovascular disease (fasting blood samples analysed at 0, 6 and 18 months)
3. Health related quality of life measured by the 36-item Short Form health survey (SF-36) at 0, 6 and 18 months
4. Day-time sleepiness and sleep quality measured by the Epworth Sleepiness Scale at 0, 6, and 18 months
5. Bone density measured by DXA at 0, 6, and 18 months
6. Predictors of increased physical activity measured at 0, 6, and 18 months (by various questionnaires)
7. Impact of physical activity on eating behaviour measured by the Eating Behavior Frequency scale (EBF) at 0, 6, and 18 months
8. Self-esteem measured by the Rosenberg Self-esteem Inventory at 0, 6, and 18 months

Completion date
01/12/2006

Eligibility

Key inclusion criteria
1. Healthy volunteers
2. Female
3. Abdominal obesity (waist circumference 88-120 cm)
4. Aged 30-60 years
5. No physician identified contraindication for physical activity
6. Working at least three days per week away from home

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
50

Key exclusion criteria
1. No motivation to increase physical activity
2. ElectroCardioGram (ECG) abnormalities

Date of first enrolment
05/02/2005

Date of final enrolment

01/12/2006

Locations

Countries of recruitment
Sweden

Study participating centre
Obesity Unit, M73
Stockholm
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Sponsor information

Organisation
Cycleurope (Sweden)

ROR
https://ror.org/02fwyek38

Funder(s)

Funder type
Industry

Funder Name
Karolinska Institute (Karolinska Institutet), Stockholm, Sweden

Funder Name
Cycleurope (Sweden)

Results and Publications

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	01/09/2010	31/12/2020	Yes	No