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Incondition

Submission date	Recruitment status	[_] Prospectively registered
26/03/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/06/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/01/2015	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Urinary incontinence (UI) is one of the major problems in older adults with a high impact on quality of life, especially among older women in long-term care facilities. Although conservative treatment for UI, such as pelvic floor muscle training (PFMT) and bladder training (BT), have been proven effective in independent older adults, current practice for women in homes for the elderly focuses on managing the consequences by providing incontinence pads and toileting assistance instead of treating underlying conditions or causes of UI such as reduced mobility. Strategies such as prompted voiding (participants urinate according to a schedule) and individual physical training have been shown to have a positive effect on frail nursing home residents. These interventions significantly reduce the frequency of incontinence episodes and improve mobility endurance even in people with mental and physical impairments. The main disadvantages of these interventions are the increased workload for nursing staff and high costs which could obstruct large-scale implementation. For these reasons it would be worthwhile to develop a strategy that targets the main causes and risk factors of UI without increasing the workload for nursing staff in long-term care facilities. To evaluate such a strategy, we developed a group-based physical exercise program to be delivered by physical therapists. It consists of exercises that target the functional causes of UI both directly by strengthening of the pelvic floor muscles and bladder training, and indirectly by improving physical performance relevant to continence behavior. The aim of this study was to evaluate the effectiveness of this group-based program by improving functional performance in older women living in homes for the elderly.

Who can participate?
Older women with or without UI and physically and mentally capable of participating in the exercise program.

What does the study involve?
The Incondition program consisted of weekly, 1-hour training sessions for groups of 610 women over a period of 22 weeks. Each session consisted of behavioral instructions and physical exercises. The behavioral element aimed to improve the control of micturition (urination) by improving knowledge about continence, improving toilet behavior (position, relaxation etc.), BT, and PFMT including relaxation and breathing. The aim of the physical exercises was to increase the functional ability to use the toilet independently and in time. Exercises were kept functional and pleasant, and used materials to enhance compliance. The 30-minute exercise session included warming up, exercises to improve the mobility of the upper extremities, hand function,

standing up and sitting down on a chair or bed, walking, and cooling down. Participants received a written leaflet containing guidelines on good toilet behavior and micturition. After each session, homework exercises were given, if possible on an individual basis, and evaluated at the start of the following session. The intervention was delivered by physical therapists specialized in PFMT and experienced in group training and affinity with older adults. The physical therapists received special training to carry out the intervention correctly. Taking part in this program for 1 year was compared with receiving care as usual (in most cases prescribing incontinence pads). Ten homes carried out the new program, ten provided care as usual.

What are the possible benefits and risks of participating?
Benefits included better physical performance to use the toilet independently and reduction of UI. Possible risks were minimal as the program was adapted to the current physical level of participants. In order to avoid the taboo surrounding UI in homes both women with and without UI could participate so it was not publicly known who had UI. If successful the program will be implemented in other homes.

Where is the study run from?
Twenty homes for the elderly will be contacted to join in this study. The Netherlands organization for applied sciences (TNO) will carry out the development and evaluation.

When is study starting and how long is it expected to run for?
The study started in February 2002 and recruitment started in 2003. The program ran for 6 months.

Who is funding the study?
It was funded by the Netherlands Health Research and Development Council, The Hague, The Netherlands.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

001

Study information

Scientific Title
Incondtion: a RCT into the effectiveness of a group based exercise program to reduce urinary incontinence in institutionalized older women

Study objectives
Reduction in the number of participants with urinary incontinence (UI) and the frequency of UI episodes in participants of the exercise program compared to those with those receiving usual care; improvement in performance relevant to continence behavior (mobility, dexterity etc).

Ethics approval required
Old ethics approval format

Ethics approval(s)
TNO Medical Ethics Committee, 17/12/2002, ref: METC 99/02

Primary study design
Interventional

Study design
Multilevel randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Physiscal performance and urinary incontinence

Interventions
Intervention: a group-based physical exercise program to be delivered by physical therapists consisting of exercises that target the functional causes of UI both directly by strengthening of the pelvic floor muscles and bladder training, and indirectly by improving physical performance relevant to continence behavior. The Incondition program consisted of weekly, 1-hour training sessions for groups of 6-10 women over a period of 22 weeks.

Control: care as usual (mainly incontinence materials)

Intervention Type
Behavioural

Primary outcome(s)
1. UI status
2. Severity of UI
3. Physical performance

Key secondary outcome(s)
Quality of life (physical, mental and incontinence-related)

Completion date
01/06/2004

Eligibility

Key inclusion criteria
1. Female
2. Having sufficient cognitive and physical function to allow them to participate in the intervention (participants with a score higher than 9.6 on the Cognitive Screening Test (CST)
3. Use of toilet independently (as measured by the Barthel Index)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Currently using catheterization

Date of first enrolment
01/01/2003

Date of final enrolment
01/06/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Wassenaarseweg 56
Leiden
Netherlands
2301 CE

Sponsor information

Organisation
Netherlands Health Research and Development Council (Netherlands)

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Government

Funder Name
Netherlands Health Research and Development Council (Netherlands) ref: 2010096440

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	06/09/2012		Yes	No