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INCONDITION; A MULTI-LEVEL RANDOMIZED CONTROLLED TRIAL OF A PROGRAMME TO REDUCE AND PREVENT URINARY INCONTINENCE IN WOMEN IN HOMES FOR THE ELDERLY

Aims of study

Aim was to evaluate a newly developed programme for women in homes for the elderly. The programme aimed to reduce episodes of urinary incontinence, improve functional performance and quality of life, and reduce caregiver burden and use of incontinence materials. A process evaluation is reported separately.

Study design, materials and methods

Participants were women in homes for the elderly, with or without urinary incontinence who were cognitively not impaired, capable of independent toileting and did not use a (indwelling) catheter.

The experimental group received a 22 week programme called INCOndition, consisting of a weekly training session of 1 hour. A session consists of education about lifestyle and bladder control, bladder training and pelvic floor muscle training followed by exercises to improve mobility. The control group received standard treatment.

Primary outcome measures were frequency and quantity of incontinence episodes as recorded by a bladder diary, Physical Performance Test (PPT), general (SF-12) and specific quality of life (IQoL and IIQ-7), caregiver burden (Barthel Index) and use of incontinence materials (3 week registration). Data were collected via interviews and registration by nurses.
To prevent contamination between the experimental and control group randomization was done on the level of the participating homes. Participants were blinded until baseline measurements were completed.

An intention-to-treat analysis was done as well as a per-protocol analysis. Due to missing data an imputed data matrix was conceived (with Mice in S-plus, version 6.1) to upgrade case numbers at follow-up. Students T-test and Chi Square tests were conducted to compare both groups at baseline. To evaluate the difference in outcome measures between experimental and control group, both general linear models for repeated measurements and linear mixed-effect models were used.

Results

Two out of 20 recruited homes dropped out because no participants could be recruited (both control group). The remaining 18 homes recruited 192 participants. In total 61 participants were lost to follow up: 21 did not start the study, 18 due to illness/death and 22 for other reasons. These 22 drop outs were characterized by a lower cognitive level (as measured by a cognitive screening test), less ADL-limitations and less chronic diseases and fewer complaints of incontinence. Non-response analysis showed no difference in drop out between experimental and control group. No differences were found at baseline between both groups except the number of chronic diseases which was higher in the experimental group. Mean age (range) was 85 years (64-95), 55% had urinary incontinence episodes.

Outcome measures:
First an intention-to-treat analysis was carried out including all participants which met the inclusion criteria and with baseline data (n=153). No differences in outcome measures were found between experimental and control group. Both groups however showed an improvement of general quality of life. Secondly a per-protocol analysis was conducted excluding dropouts and participants who did not meet inclusion criteria (n=18). Participants which attended less then 14 sessions (n=9) were excluded to create a homogenous intervention group. An imputed data set was used (n=111). Frequency and quantity of urinary incontinence episodes decreased in the experimental group with 63% and 72% respectively. In the control group frequency and quantity also decreased (50% both; no statistical

significant difference between groups). PPT scores improved with 13% in the experimental group and worsened 4% in the control group, which indicated a significant difference (F=10,1;p=.002). Generic quality of life measures showed minor increases, but no differences between groups. Incontinence related quality of life improved on the IIQ7, but decreased on the IQoL for the experimental group (no significant difference). No difference was found on the Barthel index. Numbers of used incontinence products decreased in the experimental group with 14% at follow up and rose with 13% in the control group but this did not reach a significant level.

Interpretation of results

Dropout numbers were high due to the characteristics of participants (frail elderly women) and the large study period. No differences were found between experimental and control group in the intention-to-treat analysis for all outcome measures The per protocol analysis showed some differences. Although Levels of urinary incontinence dropped in both groups, no interaction effect could be found to indicate a positive contribution of our programme. Physical performance however improved as result of the programme.

Concluding message

Doing research with frail elderly people in homes for the elderly is very demanding for participants and nursing staff, leading to relatively high numbers of drop-outs. It seems that improvement of urinary incontinence in homes for the elderly is possible. However, the contribution of the programme to this improvement was too small. Other factors may be of importance.

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