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A GENERAL PHYSICAL TRAINING PROGRAMME FOR RESIDENTS IN NURSING HOMES AND THE EFFECT ON URINARY INCONTINENCE: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

The aim of this study was to investigate if an individualized training programme designed to improve activity of daily living (ADL) and physical capacity among residents in nursing homes, had any impact on urinary incontinence (UI).

Study design, materials and methods

This randomized controlled trial was a sub-study of the Nordic multi-centre study "Physical Functioning and Activity of Daily Living among Residents in Nursing Homes" (1). Results in the present sub-study comprise data from four general public nursing homes from fall 2005 to spring 2006. Inclusion criteria: The participants had to be more than 65 years of age, stayed in the nursing home for more than three months, and in need of assistance in at least one ADL activity. Residents with life expectancy less than six months were excluded. A total of 98 residents were included, and randomly allocated to a training group (n=48) or a control group (n=50). Randomization was carried out directly after baseline measurements within each nursing home ward. The training programme, which included accommodated physical activity and ADL-training, was individually adjusted for each resident in the intervention group and lasted for 3 months. The programme was implemented by hired physiotherapists (two) and occupational therapists (two). The control group maintained the same offer they already received. The main outcome measure in this sub-study was UI as measured by the daily amount of leakage. There was no statistically significant difference between the groups on this measure at baseline (p-value 0.57). A 24-hours pad-weighing test was used to get information about UI at baseline, immediately after the intervention and three months after the intervention (test 3). Staff members on each unit were responsible for completing the tests. Changes were calculated from baseline to test 3. Because we joined a beforehand designed multi-centre study, the study population was already decided based on sample size estimation for the multi-centre study. Sample size estimation for the present sub-study was therefore not calculated.

<u>Results</u>

The numbers of participants included in the analysis were 35 in the intervention group and 33 in the control group. The average age was 84.4 years; there were no statistically significant differences between groups and gender according to age. The number of non-response at test 3 was 30 (13 in the intervention group and 17 in the control group). Reasons for dropping out of the study are listed in table 1.

| | Intervention group | Control group |
|--|--------------------|---------------|
| Participants at baseline | 48 | 50 |
| - Dead | 4 | 6 |
| - Withdraw or moved | 7 | 4 |
| - Not interpretable or incomplete data | 2 | 7 |
| Participants in the analysis | 35 | 33 |

Table1. Reasons for non-response during the study

As shown in table 2, the decrease of leakage in the intervention group was not statistically significant, but there was a statistically significant increase of leakage in the control group. Analyses were done separately among women and men, and showed the same tendency in both genders.

Table 2. Daily amount of leakage at baseline and test 3

| | Leakage (gram) | Leakage (gram) | |
|---------------------------|----------------|----------------|-------|
| | Baseline | Test 3 | |
| Intervention group (n=35) | 576 | 489 | 0,567 |
| Control group (n=33) | 424 | 624 | 0,007 |

Wilcoxon Signed Ranks Test

Interpretation of results

The numbers of non-response at test 3 is a matter of concern. Even though residents with life expectancy less than six months were excluded from the study, altogether 10 patients died during the study. This emphasizes the fact that the population in this study was frail older persons, with multiple medical diagnosis, multiple medications, and needed help to perform some or all ADL. Reasons for withdrawal from the study might be that the training programme required an active involvement from the participants, and it is reasonable to assume that this effort can explain why some residents dropped out during the study period. A 24-hours pad-weighing demanded an effort from staff members on day- evening- and night shifts, as they had to understand how to complete the test and adhere to do so. Hence, lack of adherence may explain the numbers of not interpretable or incomplete data at test 3. The total number of drop outs is considerable, and we do not know if, to what extent, or in which direction this has influenced the results. We have documented that UI increases rapidly in nursing home residents. It is therefore important to address this problem in order to prevent worsening. Despite the lack of evidence of UI improvement in

the training group, it is notable that UI remained stable. For nursing home residents, their medical, physical, and mental state decline over time, and it might be unrealistic to expect UI improvement. However, we anticipate that this result reflects the fact that the training programme was too general to have adequate impact on UI in this group of frail elderly residents. It is more likely to believe that a more goal-oriented physical training programme towards residents with UI would have lead to a decrease of leakage.

Concluding message

Residence in nursing homes is a risk factor for worsening UI. An individualized training programme designed to improve ADL and physical capacity, may prevent this worsening but is not sufficient to improve UI. Further studies are needed to evaluate the effect of a goal-oriented physical training programme towards nursing home residents UI complaints, as well as evaluate the effect of other behavioural interventions (2, 3). These trials should also include residents' quality of life, staff satisfaction, and cost outcomes (3).

References

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- 3. Fink HA, Taylor BC, Tacklind JW, Rutks IR, Wilt TJ. Treatment interventions in nursing home residents with urinary incontinence: A systematic review of randomized trials. Mayo Clin Proc 2008; 83(12): 1332-43

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|--|---|--|--|
| Is this a clinical trial? | Yes | | |
| Is this study registered in a public clinical trials registry? | Yes | | |
| Specify Name of Public Registry, Registration Number | ClinicalTrials.gov Protocol Registration System, (203-04) NCT00218842 | | |
| Is this a Randomised Controlled Trial (RCT)? | Yes | | |
| What were the subjects in the study? | HUMAN | | |
| Was this study approved by an ethics committee? | Yes | | |
| Specify Name of Ethics Committee | Regional Committees for Medical and Health Research Ethics, REK 4, Norway (203-04) | | |
| Was the Declaration of Helsinki followed? | Yes | | |
| Was informed consent obtained from the patients? | Yes | | |