UKE Paper of the Month August 2015

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Home-based constraint-induced move-ment therapy for patients with upper limb dysfunction after stroke (HOMECIMT): a cluster-randomised, controlled trial

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ABSTRACT:

Background: Constraint-induced movement therapy (CIMT) is recommended for patients with upper limb dysfunction after stroke, yet evidence to support the implementation of CIMT in ambulatory care is insufficient. We assessed the efficacy of home CIMT, a modified form of CIMT that trains arm use in daily activities within the home environment.

Methods: In this parallel, cluster-randomised controlled trial, we selected 71 therapy practices in northern Germany that treat adult patients with upper limb dysfunction after stroke. Practices were stratified by region and randomly allocated by an external biometrician (1:1, block size of four) using a computer-generated sequence. 37 practices were randomly assigned to provide 4 weeks of home CIMT and 34 practices to provide 4 weeks of standard therapy. Eligible patients had mild to moderate impairment of arm function at least 6 months after stroke and a friend or family member willing to participate as a non-professional coach. Patients of both groups received 5 h of professional therapist contact in 4 weeks. In the home CIMT group, therapists used the contact time to instruct and supervise patients and coaches in home CIMT. Patients in the standard therapy group received conventional physical or occupational therapy, but additional home training was not obligatory. All assessments were done by masked outcome assessors at baseline, after 4 weeks of intervention, and at 6 month follow-up. The primary outcomes were quality of movement, assessed by the Motor Activity Log (MAL-QOM, assessor-assisted self-reported), and performance time, assessed by the Wolf Motor Function Test (WMFT-PT, assessor-reported). Primary outcomes were tested hierarchically after 4 weeks of intervention and analysed by intention to treat, using mixed linear models. This trial is registered with Clinical-Trials.gov, NCT01343602.

Findings: Between July 11, 2011, and June 4, 2013, 85 of 156 enrolled patients were assigned home CIMT and 71 patients were assigned standard therapy. 82 (96%) patients in the home CIMT group and 71 (100%) patients in the standard therapy group completed treatment and were assessed at 4 weeks. Patients in both groups improved in quality of movement (MAL-QOM; change from baseline 0·56, 95% CI 0·41–0·71, p<0·0001 for home CIMT vs 0·31, 0·15–0·46, p=0·0003 for standard therapy). Patients in the home CIMT group improved more than patients in the standard therapy group (between-group difference 0·26, 95% CI 0·05–0·46; p=0·0156). Both groups also improved in motor function performance time (WMFT-PT; change from baseline −25·60%, 95% CI −36·75 to −12·49, p=0·0006 for home CIMT vs −27·52%, −38·94 to −13·94, p=0·0004 for standard therapy), but the extent of improvement did not differ between groups (2·65%, −17·94 to 28·40; p=0·8152). Nine adverse events (of which six were serious) were reported in the home CIMT group and ten (of which seven were serious) in the standard therapy group; however, none was deemed related to the study intervention.

Interpretation: Home-based CIMT can enhance the perceived use of the stroke-affected arm in daily activities more effectively than conventional therapy, but was not superior with respect to motor function. Further research is needed to confirm whether home CIMT leads to clinically significant improvements and if so to identify patients that are most likely to benefit.

STATEMENT:

The HOMECIMT trial represents an important contribution to research in the long-term care of stroke patients. In fact, this is the first sufficiently powered, randomised controlled trial, which assessed the efficacy of modified constraint-induced movement therapy (home CIMT) in ambulatory care of chronic stroke patients. Moreover, as specialists for primary medical care we performed one of the first randomised controlled trials with therapy practices in Germany, and we were able to demonstrate an excellent recruitment and retention rate under ambulatory care conditions.

CIMT is one of the most promising and empirically supported approaches to improve upper limb dysfunction in stroke patients. The UKE has particular experience in original CIMT, which is provided since more than 15 years at the UKE Physiotherapy. However, due to a high staff-to-patient ratio original CIMT is not applicable in ambulatory care. Also, CIMT is mainly offered to direct payers, because costs are usually not covered by health care insurances. Thus, we developed and evaluated the modification home CIMT that is adapted to ambulatory care conditions to provide this participation-oriented, therapeutic concept to the treatment of patients with chronic stroke-related dysfunction in long-term care.

In the HOMECIMT trial, we showed that 4 weeks of home CIMT can improve self-reported quality of arm use in activities of daily living in patients with upper limb dysfunction after stroke compared with standard physical or occupational therapy. Home CIMT represents a unique therapeutic approach by adapting modified CIMT for stroke rehabilitation into clinical practice. Our findings provide a basis for future stroke research

BACKGROUND:

This work is the result of an interdisciplinary UKE researcher group and was performed under the guidance of Dr. Anne Barzel (Department of Primary Medical Care) in cooperation with Gesche Ketels (UKE Physiotherapy), and in collaboration with the Department of Medical Biometry and Epidemiology (study design, data analysis) and the Department of Neurology (scientific advisory board). We both have strong research interests in ambulatory care of stroke patients. The study was part of the Master thesis of Anne Stark. It was supported by the BMBF (FKZ-01-GX-1003) funding priority for health care-related research “Chronic diseases and patient orientation”.