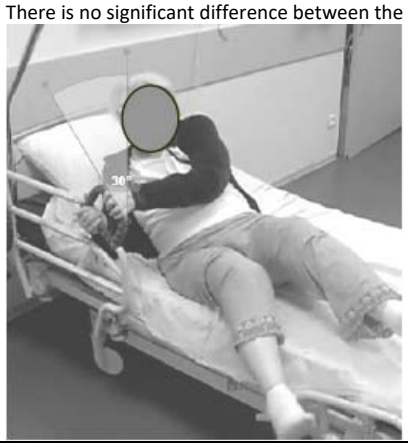
EVALUATION OF MOBILITY AID SYSTEM (SAM ERGONOM) - TABULATED SUMMARY UPDATED ON 01/03/2017

DESCRIPTION	
Study Title	Evaluation of the influence of the "SAM ERGONOM" bed mobility aid device on the mobility of elderly patients (≥ 65 years old): a randomised, single-centre study.
Type of study	A prospective, single-centre, randomised study comparing two medical devices (SAM Ergonom versus lifting column)
Study Date	2015
Sponsor	CHU (Centre Hospitalier Universitaire [University Hospital Centre]) of Nîmes, Department of Research and Innovation
Principal investigator	Dr VIOLLET, Department of Physical Medicine and Physical Rehabilitation, CHU of Nîmes
Methodologist	Dr Dematteï (PhD), Department of Biostatistics, Clinical Epidemiology, Public Health, Medical Information (BESPIM [Biostatistique, Epidémiologie, Santé Publique et Informatique Médicale]), CHU of Nîmes
Investigation site(s)	CHU of Nîmes, Physical Medicine and Physical Rehabilitation
Other information	Clinical study NCT01746433 Patent No. EP2617403-24/07/2013
METHOD	
Inclusion criteria	Patients older than sixty-five years, stable medical condition, no cognitive deficit, difficulty in performing "lying-sitting" transfers in less than ten seconds, with a postural balance of 2 out of 4*, consent. **Level 2 according to the Postural Balance Scale: Seated postural balance maintained without back support, but loss of balance if pushed, irrespective of the direction.*
Primary endpoint	Transfer from lying position to sitting position in less than ten seconds (Success/Failure; %)
Secondary endpoints	Necessary time to sit down (min) and evaluation of the movement of the mass centre during the action of sitting.
Sample size	38 patients
Randomisation	19 patients in the exposed group (SAM), 19 patients in the control group (lifting column)
Analysis of the results	Statistical analysis.
Abbreviations	NA Not applicable. F: Female. M: Male.
RESULTS	
Subjects analysed	38 patients
Follow-up period	NA
Characteristics Of the patients included	F/M distribution: 1.92 Average age 84.7 years (71; 93)
Experimental protocol	Positioning of the patient: bedridden, centred pelvis, greater trochanter at the level of the joint of the headrest two consecutive attempts (Learning, timed observation phase).
Primary endpoint	"Lying-sitting" transfer successful for 89.5% of the patients of the SAM Ergonom group versus 68% for the lifting column. 17 successes with SAM and 2 failures versus 13 successes and 6 failures with the lifting column. In one case out of three, the lifting column do not help with the "Lying-Sitting" transfer. The difference between the two systems is significant.
Secondary endpoints	Necessary time to sit down: 12,5 seconds (4;24) in the SAM group; 12 seconds (5;20) in the lifting column group. There is no significant difference between the two systems. 
Side effects	None.
CONCLUSION	
The SAM Ergonom device was designed to help the elderly with difficulties in performing the "Lying-Sitting" transfers. Its principle is to improve lateral rotation and trunk flexing by bringing the mass centre close to the edge of the bed. The results of this study show that this device improves the "Lying-Sitting" recovery motor diagram of the patients included. SAM may influence the motor strategy during psychomotor regression syndrome by bringing the mass centre to an anterior rotation in 90% of the cases for the first five seconds versus 50% in retropulsion among the patients using lifting columns.	

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