CLINICAL TRIAL

- Prospective, observational, non-interventional, multicentre Clinical Study. Descriptive analysis.
- Date of study: 2013 to 2014. Place of the study: health and medico-social establishments on French territory, and Home Care. Sample size: 30 patients
- Average age: 81 years; sex-ratio: W/M 2,3; Initial average BMI: 25 (15 ; 40)
- Average period spent bed-ridden: 20 hours (12 ; 24); Average daily number of times turned over: 3,8; persons raised at least once per day
- Average initial Norton score: 9; 73% patients presenting one or more pressure ulcers
- 35 pressure ulcers: 49% sacrum, 40% heels; 80% stage 1-2, 20% stage 3-4
- Main pathologies identified: neurology, cardiovascular, pneumology, orthopaedics, endocrinology
- Assessment at D₀ ans D_{END}. Average duration of monitoring: 23 days

METHOD

RESULTS

- **MAIN JUDGEMENT CRITERIA**: Onset or non-onset of pressure ulcer(s)
  - No onset of pressure ulcers, 24 instances of favourable progress (69%), 11 stabilised conditions (31%)

- **SECONDARY JUDGEMENT CRITERIA**: tolerance levels by criterion

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Satisfied</th>
<th>Unsatisfied</th>
<th>NR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ergonomics</td>
<td>71%</td>
<td>0%</td>
<td>29%</td>
</tr>
<tr>
<td>MMI</td>
<td>56%</td>
<td>1%</td>
<td>43%</td>
</tr>
<tr>
<td>Safety</td>
<td>60%</td>
<td>1%</td>
<td>39%</td>
</tr>
<tr>
<td>Comfort</td>
<td>61%</td>
<td>5%</td>
<td>33%</td>
</tr>
</tbody>
</table>

MMI: Man-Machine Interface; NR: Not Recorded

UPDATED ON 01/03/2017