Randomized Controlled Trial for Low Back Pain

- **AT 10 WEEKS**, ViMove patients showed significant improvement in all key measures. Improvements were sustained or improved at 12 months.

- More than **3X** more likely to have clinically important improvements (>30% over baseline) in pain reduction vs. standard care at 12 months.¹

- **2.5X** more likely to have clinically important improvements (>30% over baseline) in activity limitation vs. standard care at 12 months.²

¹ Quadruple Visual Analogue Scale (QVAS)
² Patient Specific Functional Scale (PSFS)
ViMove is a wireless medical device that measures, records, and reports movements and muscle activity of the lower back / lumbar spine. The system also measures range of motion in the sagittal and coronal anatomical planes.

ViMove vs. Guidelines-Based Care: Can modifying movement patterns using wearable sensors and biofeedback lead to reduced pain and improvements in activity limitation?

10 WEEKS OF TREATMENT. ONE YEAR OF FOLLOW-UP.

Primary Endpoints

PAIN:

- Change over time from baseline of severity of pain measured by the Quadruple Visual Analogue Scale (QVAS)

ACTIVITY LIMITATION:

- Change over time from baseline in activity limitation, measured by the Rolland Morris Disability Questionnaire (RMDQ-23)
- Change over time from baseline in activity limitation measured by the Patient Specific Function Scale (PSFS)
### Inclusion Criteria

Participants meeting all of the following criteria were eligible for participation in the study:

1. Provision of written informed consent.
2. Between 18 and 65 years of age.
3. At least moderate intensity lower back pain (LBP) as defined by a QVAS score > 3 out of 10 (or 30mm out of 100mm) (Carragee & Chen, Spine 2000).
4. Identified by the Investigator as Sub-Acute (3 to 12 weeks post onset of LBP) or Chronic (> 12 weeks post onset of LBP).

See FAQ for Exclusion Criteria.

### Study Design

**Enrollment**

- CLUSTERS N=8 CENTERS
- RANDOMIZED PATIENTS N=112

**Baseline**

- ViMove
  - 4 CENTERS
  - RANDOMIZED PATIENTS N=58
- Guidelines-based Care
  - 4 CENTERS
  - RANDOMIZED PATIENTS N=54

**Treatment & Follow-Ups**

- 6-8 treatments over 10 weeks
  - FOLLOW-UPS AT 3, 6, 12 MONTHS

Both arms received standard guidelines based care including advice on staying healthy and general self-management, of back pain. All participants wore ViMove sensors 4-10 hours in their activities of daily living during and after each treatment session over 10 weeks (6-8 times). Control arm wore placebo sensors.

### Interventions during the trial: ViMove Arm vs Control

**ViMove ARM INTERVENTION:**

- Individualized ViMove guided assessment of movement to determine connection between movement and pain. Assessment drove patient-tailored specific rehabilitation strategies.

- Sensors were worn by patients outside clinic and data collected on % time slouching, sitting/standing, and degrees in flexion to guide clinician care.

- Wearing ViMove sensors and watching real-time graphical feedback on movement, patients were instructed on how to alter movements patterns to avoid pain.

- Sensors worn by patients during daily living. Using ViMove software, clinicians could easily program motion sensor biofeedback alerts (audio, vibration) to alert if patient exceeded a desired range of motion. Patients were then alerted, by ViMove sensors when they “broke a rule” that clinician had programmed.
Study Results

“These results are unusual and encouraging because they show moderate to large effects at the end of the 10-week treatment period that remained or increased at the 12 month follow-up, in a health condition where interventions typically show small to moderate effects that are not sustained 12 months later.”

- STUDY AUTHORS

Roland Morris Disability Questionnaire 23 (RMDQ-23)

ViMove PATIENTS 2.4X MORE LIKELY TO HAVE CLINICALLY IMPORTANT IMPROVEMENTS VS STANDARD CARE AT 12 MONTHS*

The Roland Morris Disability Questionnaire 23 was used to assess the subject's functional ability. This questionnaire asks 23 questions relating to the subject's activities of daily living and their ability to perform these activities. Participants responded either “Yes” or “No” to each question, with a score of “1” applied to “Yes” and a score of “0” applied to “No.” Using proportional recalculation, RMDQ-23 scores were transformed into a 0–100 scale (0 = no activity limitation, 100 = maximum activity limitation).**

* Unadjusted risk ratios
** Lower score indicates better movement function

Patient Specific Functional Scale (PSFS)

ViMove PATIENTS 2.5X MORE LIKELY TO HAVE CLINICALLY IMPORTANT IMPROVEMENTS VS STANDARD CARE AT 12 MONTHS*

The PSFS is a scale used to assess functional activity where participants are asked to identify three functional activities that were important to them and with which they were experiencing some activity limitation. On a scale of 0–10, participants scored from “0” (unable to perform activity) to “10” (able to perform activity at the same level as before injury or problem) for each of the activities. Raw scores were proportionally recalculated and reversed to create a 0–100 scale (0 = no activity limitation, 100 = maximum activity limitation).**

* Unadjusted risk ratios
** Lower score indicates better movement function

Quadruple Visual Analogue Scale (QVAS)

ViMove PATIENTS 3.3X MORE LIKELY TO HAVE CLINICALLY IMPORTANT IMPROVEMENTS VS STANDARD CARE AT 12 MONTHS*

The QVAS is a scale that measures levels of pain and consists of four questions each with a horizontal line of 100 mm in length below and a scale of “0” (no pain) to “100” (worst possible pain). The participant marked on the line the point that they felt represented their perception of their pain. The anchors for all four questions were 0 = “no pain” and 100 = “worst possible pain.”**

* Unadjusted risk ratios
** Lower score indicates reduction in pain intensity
Medication usage and other interventions

“For LBP analgesics use, there was a significant group-by-time effect. For every 10 days in the 72-day treatment period, the proportion of days reported taking analgesics reduced by 0.007 more in the Movement Biofeedback Group, than in the Guidelines-Based Care Group.”

“There were significant group and group-by-time effects on the number of pain and medication-free days. The proportion of pain and analgesics medication-free days over the 72-day treatment period was 0.042 more in the Movement Biofeedback Group than in the Guidelines-Based Care Group. Also, for every 10 days in the treatment period, the proportion of days reported as not having pain or taking any analgesics increased by 0.004 more in the Movement Biofeedback Group than in the Guidelines-Based Care Group.”

- STUDY AUTHORS

Co-Interventions received during intervention period

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>MOVEMENT BIOFEEDBACK GROUP</th>
<th>GUIDELINES-BASED CARE GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of patients receiving each intervention type</td>
<td>Mean number of treatments per patient</td>
</tr>
<tr>
<td>Advice or education</td>
<td>18 (31.0 %)</td>
<td>0.58 (SD 1.02)</td>
</tr>
<tr>
<td>Exercise</td>
<td>32 (55.2 %)</td>
<td>1.40 (SD 1.77)</td>
</tr>
<tr>
<td>Imaging</td>
<td>3 (5.2 %)</td>
<td>0.07 (SD 0.33)</td>
</tr>
<tr>
<td>Manual Therapy</td>
<td>36 (62.1 %)</td>
<td>1.89 (SD 1.98)</td>
</tr>
<tr>
<td>Medication</td>
<td>6 (10.3 %)</td>
<td>0.16 (SD 0.53)</td>
</tr>
<tr>
<td>Other</td>
<td>15 (25.9 %)</td>
<td>0.35 (SD 0.74)</td>
</tr>
<tr>
<td>Taping or Bracing</td>
<td>1 (1.7 %)</td>
<td>0.02 (SD 0.13)</td>
</tr>
</tbody>
</table>
WHAT WERE SECONDARY ENDPOINTS?

Secondary endpoints included daily pain score, LBP analgesics use, number of pain free and medication free days, LBP recurrence, time away from work or usual daily activity, care seeking for LBP outside the treatment in the trial, fear avoidance, learned pain behavior, or lack of confidence. Restrictive settings were established to avoid “high risk” movement patterns and positions.

WHAT WERE THE EXCLUSION CRITERIA FOR THE TRIAL?

Exclusion criteria included the following conditions:
1. Lower back surgery within previous 12 months.
2. Pregnant females.
3. Participants with a severe hearing impairment.
4. Evidence of non-mechanical contributing cause for LBP (e.g. neoplasm, infection, fracture, inflammatory disorder).
5. Preceding chronic neurological changes (sub-acute group only).
6. Implanted electrical medical device (spinal cord stimulator, intrathecal pump, pacemaker or peripheral nerve stimulator)
7. Nerve block, spinal injection, or anesthetic procedure for the treatment of lower back pain, within 12 months of the study.
8. Significant medical abnormalities or conditions that in the opinion of the investigator would interfere either with the ability to complete the study or the evaluation of the investigational device’s safety and efficacy.
9. Recent history of a significant medical-surgical intervention that in the judgment of the investigator would interfere either with the ability to complete the study or the evaluation of the investigative device’s safety and efficacy.
10. Known allergy (skin reaction) to tapes and plasters.
11. Currently enrolled in an investigational drug or device study.

WHAT TYPE OF CLINICIANS PARTICIPATED IN THE TRIAL?

Clinicians included Physiotherapists, General Practitioners, Pain Physicians and Musculoskeletal Physicians.

WHO FUNDED THE TRIAL?

The trial was co-funded by the Victorian State Government and dorsaVi. Analysis and interpretation of the data was completely independent of both industry and governmental sponsors. Neither sponsor was sent or requested any version of trial paper prior to publication. All three authors were paid from the funding provided by the Victorian State Government and dorsaVi, a market-rate consulting fee for participating in various phases of the project. Neither funding entity had any influence over how these data were presented and the conclusions reached.

WHAT WERE THE STUDY LIMITATIONS?

The authors describe some limitations with the study. This included co-funding by the government and manufacturer, however analysis and interpretation of the results was completely independent of both the government and industry sponsors, and additional governance functions were provided to safeguard and ensure that the trial maintained scientific rigour. Other limitations described in the paper include lack of clinician blinding and potential selection bias, although the only difference between the groups at baseline was age, which was adjusted for in the longitudinal analysis.