dorsaVi™

INSPIRING THE WORLD TO MOVE WELL™

ViMove™

Randomised 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™

CLINIC SOLUTIONS

To learn more visit dorsaVi.com.

ViMove MUSCLE ACTIVITY SENSORS / ACTUAL SIZE

ViMove MOVEMENT SENSORS / ACTUAL SIZE

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.

Kent *et al. BMC Musculoskeletal Disorders* (2015) 16:131
DOI 10.1186/s12891-015-0591-5

BMC Musculoskeletal Disorders

RESEARCH ARTICLE Open Access

The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain-*a multicentre, cluster-randomised, placebo-controlled, pilot trial*

Peter Kent[1,2*], Robert Laird[3] and Terry Haines[3,4]

Study Aim: What's the impact of treating low back patients with ViMove vs. Guidelines-Based Care?

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

Primary Endpoints

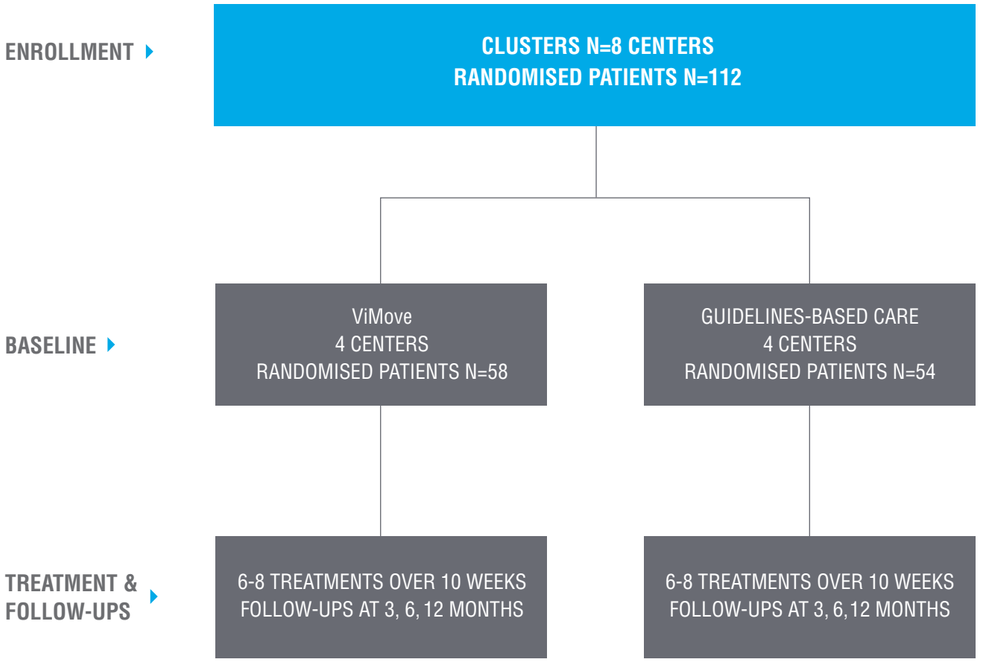
PAIN:

- 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)

Study Design



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.

Interventions during the trial: Treatment Arm vs Control

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.

ViMove TREATMENT ARM INTERVENTION:

ViMove LIVE ASSESSMENT	*Individualised ViMove guided assessment of movement to determine connection between movement and pain. Assessment drove patient-tailored specific rehabilitation strategies.*
ViMove LIVE TRAINING	*Sensors were worn by patients outside clinic and data collected on % time slouching, sitting/standing, and degrees in flexion to guide clinician care.*
ViMove MONITORING	*Wearing ViMove sensors and watching real-time graphical feedback on movement, patients were instructed on how to alter movements patterns to avoid pain.*
ViMove BIOFEEDBACK	*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.*

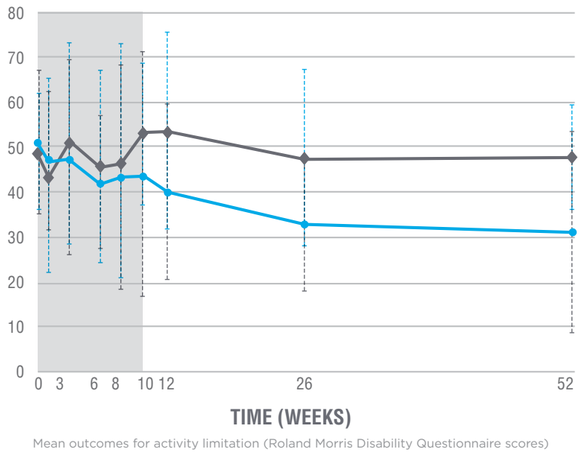
Study Results

"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*



Mean outcomes for activity limitation (Roland Morris Disability Questionnaire scores)

"Clinically important events" defined as >30% improvement vs baseline

GUIDELINES-BASED CARE GROUP

MOVEMENT BIOFEEDBACK GROUP

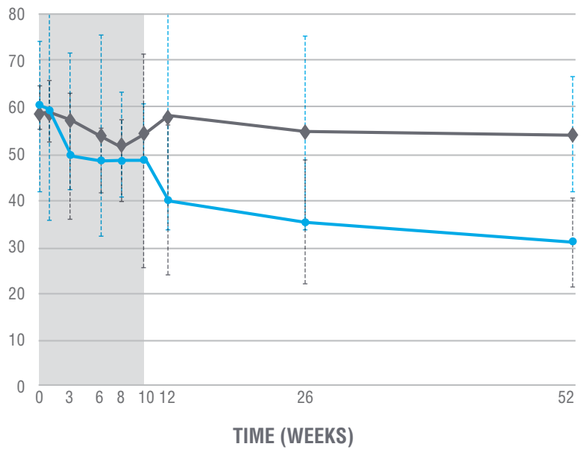
The Roland Morris Disability Questionnaire 23 was used to assess the subject's functional ability. This questionnaire asks 23 questions relating to the subject's activities of daily living and their ability to perform these activities. Participants responded either "Yes" or "No" to each question, with 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*



Mean outcomes for activity limitation (Roland Morris Disability Questionnaire scores)

"Clinically important events" defined as >30% improvement vs baseline

GUIDELINES-BASED CARE GROUP

MOVEMENT BIOFEEDBACK GROUP

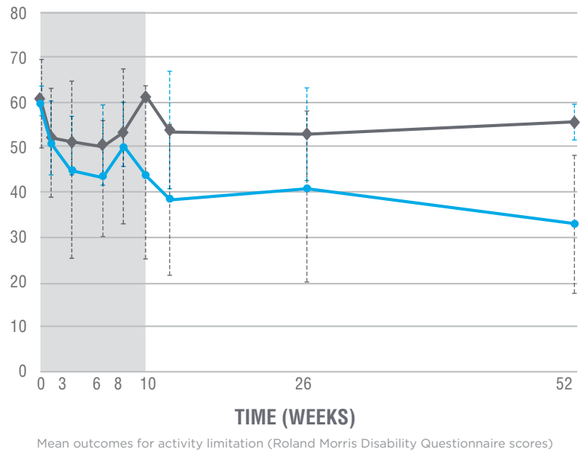
The PSFS is a scale used to assess functional activity where participants are asked to identify three functional activities that were important to them and with which they were experiencing some activity limitation. On a Scale of 0-10, participants scored from "0" (unable to perform activity) to "10" (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*



Mean outcomes for activity limitation (Roland Morris Disability Questionnaire scores)

"Clinically important events" defined as >30% improvement vs baseline

GUIDELINES-BASED CARE GROUP

MOVEMENT BIOFEEDBACK GROUP

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

	MOVEMENT BIOFEEDBACK GROUP		GUIDELINES-BASED CARE GROUP	
Intervention Type	Number of patients receiving each intervention type	Mean number of treatments per patient	Number of patients receiving each intervention type	Mean number of treatments per patient
Advice or education	18 (31.0 %)	0.58 (SD 1.02)	19 (35.2 %)	1.48 (SD 2.62)
Exercise	32 (55.2 %)	1.40 (SD 1.77)	40 (74.1 %)	4.78 (SD 3.25)
Imaging	3 (5.2 %)	0.07 (SD 0.32)	8 (14.8 %)	0.13 (SD 0.34)
Manual Therapy	36 (62.1 %)	1.89 (SD 1.98)	30 (55.6 %)	1.26 (SD1.73)
Medication	6 (10.3 %)	0.16 (SD 0.53)	36 (66.7 %)	2.91 (SD 2.96)
Other	15 (25.9 %)	0.35 (SD 0.74)	8 (14.8 %)	0.20 (SD 0.56)
Taping or Bracing	1 (1.7 %)	0.02 (SD 0.13)	2 (3.7 %)	0.02 (SD 0.14)

Frequently Asked Questions

WHY DID THE STUDY INVESTIGATORS CHOOSE A CLUSTER RANDOMISED TRIAL DESIGN?

The investigators believed there was a reasonable possibility of contamination in the control group (ViMove disabled) thus blinding was not considered feasible. The eight sites were randomly assigned to treatment group (ViMove) or control group (ViMove disabled) with all participants at the site being in the same group. All randomisation was performed by an independent statistician.

HOW LONG DID SUBJECTS WEAR THE SENSORS DURING TREATMENT SESSIONS?

All participants wore the ViMove movement sensor system for 4 - 10 hours during and after each treatment session (6-8 times) over the 10-week treatment period.

HOW OFTEN WERE THE PAIN AND FUNCTIONAL SURVEYS ADMINISTERED TO PATIENTS?

The surveys were administered to patients at baseline and throughout the trial to track progress. The surveys administered includes the following evidence-based instruments:

- *The Roland Morris Disability Questionnaire (RMDQ-23): Initial Assessment, Weeks 1, 3, 6, 8, 12, 26, 52*
- *Patient Specific Functional Scale (PSFS): Initial Assessment, Weeks 1, 3, 6, 8, 12, 26, 52*
- *Quadruple Visual Analogue Scale (QVAS): Initial Assessment, Weeks 1, 3, 6, 8, 12, 26, 52*
- *Fear and Avoidance Beliefs Questionnaire (FABQ): Initial Assessment, Weeks 6 and 12*
- *Daily Pain Score: Initial Assessment; Daily Diary*
- *Participants Global Impression of Change (PGIC): Week 52*

WHAT TREATMENT WAS DELIVERED TO STUDY PARTICIPANTS?

At each visit, all participants were provided with guidelines-based care for management of non-specific low back pain. This included advice on staying active and general self-management of back pain. Investigators also noted additional routine care delivered may have included exercise, manual therapy, and medication (See Table 2 in the publication for breakdown of all treatments delivered).

Participants in the ViMove treatment arm were provided with instructions on the biofeedback process (e.g. tone or vibration). Participants in the control group (placebo sensors) were not provided with instructions on the biofeedback process as they did not receive biofeedback directly from the device. The aim of biofeedback was to facilitate and encourage movement into positions that were potentially being avoided due to fear avoidance, learned pain behavior, or lack of confidence. Restrictive settings were established to avoid “high risk” movement patterns and positions.

WHAT WERE SECONDARY ENDPOINTS?

There were 8 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 of movement, and patient global impression of change. In addition, investigators used ViMove to record change in range of movement over the treatment period. See Table 4 in the publication for outcomes and discussion.

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.*

WERE THERE ADVERSE EVENTS (AES) IN THE TRIAL?

Across the 629 total consultations, there were 17 reported instances (2.7%) of device-related side effects. All involved some form of transient skin irritation from the hypoallergenic tape used to mount a movement-sensor.

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.