

**Immediate and short-term effects of a Mulligan “sustained natural apophyseal glides” for a subgroup of low back pain patients: A randomized placebo controlled trial**

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***Short-term effects of Mulligan mobilization with movement on pain, disability, and kinematic spinal movements in patients with non-specific low back pain: A randomized placebo controlled trial***

**ABSTRACT:**

**Objective**

To determine the efficacy of lumbar Mulligan sustained natural apophyseal glides (SNAGs) in patients with non-specific low back pain (LBP) with respect to two new kinematic algorithms (KA) for range of motion (KA-R) and speed (KA-S) as well as pain, functional disability, and kinesiophobia.

**Methods**

This was a randomized placebo controlled trial with two arms in accordance with CONSORT-guidelines. 87 subjects with non-specific LBP were assessed and 32 fulfilled criteria for the application of lumbar SNAGs. Subjects, blinded to allocation, were randomized to 2 groups; real-SNAG (n=16) and sham-SNAG (n=16). All patients were treated during a single-session of real/sham SNAG (3 X 6 repetitions) to the lumbar spine in a sitting position in a flexion direction. Two new KA from a validated kinematic spine model were used and recorded with an optoelectronic device. Pain at rest and during flexion, as well as functional disability and kinesiophobia were recorded by self-reported measures. These outcomes were blindly evaluated before, after treatment, and at 2-week follow-up in both groups.

**Results**

4 of 6 variables demonstrated significant improvement with moderate to large effect-sizes (ES) in favor of the Real-SNAG group: KA-R (p=.014; between groups ES Cliff's delta=-.52), pain at rest and during flexion (VAS: p<.001; ES=-.73/-.75), functional-disability (Oswestry Disability Index (ODI): p=.003 and ES=-.61). Kinesiophobia was not considered to be significant (Tampa scale: p=.03) but presented moderate effect size ES=-.46. KA-S was not significantly different between groups (p=.118) with a small ES of -.33. All the 6 outcome measures were significantly different (p≤.008) during within group analysis (before and after treatment) only in the Real-SNAG group. No serious or moderate adverse events were reported.

**Conclusion**

This study provides evidence that lumbar spine's SNAGs have a short-term favorable effect on KAR, pain and function in a targeted group of patients with non-specific LBP. Further studies are required to validate these findings and to further investigate kinesiophobia and KA-S, as well as the long-term effects of SNAGs for LBP.

## **Introduction**

Low back pain (LBP) is one of the most common musculoskeletal disorders for which patients consult medical care.<sup>1</sup> It is also the most important cause of disability and absenteeism with increasing prevalence leading to a major socio-economic impact on society.<sup>2-4</sup> These facts highlight the importance of finding effective and validated treatments for this disabling condition.

Two broad categories of LBP are recognized. When a specific patho-anatomical origin is identified such as a tumor or fracture, LBP is labelled as specific and requires appropriate medical care such as specific medication or surgery. On the other hand and more commonly, in up to 90% of cases no precise specific origin for pain can be identified; such LBP is consequently described as non-specific.<sup>1</sup>

LBP is managed by a variety of treatment modalities<sup>5,6</sup> including Orthopaedic Manual therapy (OMT). This form of treatment has been recommended in national guidelines, for example in the United States,<sup>7</sup> and is also frequently used in clinical practice in various countries.<sup>8,9</sup> As demonstrated by recent systematic reviews, OMT management combined with usual medical care provides better results as compared to usual medical care alone for all stages (acute/subacute or chronic) of LBP.<sup>7,10</sup>

A novel growing concept in the field of OMT and clinical practice, which remains sparsely studied in the literature, is "Mobilization With Movement" (MWM),<sup>11-13</sup> originally developed by Mulligan.<sup>11</sup> The main indication for MWM is movement impairment due to pain and/or stiffness. The therapeutic goal is to rapidly reduce pain and to increase range of motion (ROM). The principle of this treatment is simple, in that the manual therapist performs a sustained passive segmental glide of the involved joint, while the patient actively moves in the impaired direction.<sup>11-13</sup> Mulligan<sup>11,12</sup> purported a biomechanical basis for the

efficacy of MWM in reducing pain and improving ROM, but there may be other explanations for their effects including neurophysiological mechanisms. Mulligan MWM techniques can be applied to both peripheral and spinal joints. When applied to the spine, MWM are called Sustained Natural Apophyseal Glides (SNAGs).<sup>11-13</sup> The current study focuses on SNAGs and their effects on the lumbar spine.

It has been reported that many physical therapists in the UK manage their patients with LBP by using SNAGs as a part of their physical intervention.<sup>14</sup> This is despite the poor level of evidence, through lack of clinical studies, for the efficacy of lumbar SNAGs for LBP.<sup>15</sup> Indeed, only three studies reported on the effects of lumbar SNAGs,<sup>16-18</sup> with only 2 investigating the biomechanical effects.<sup>16,17</sup> The first, a placebo controlled trial<sup>16</sup> was carried out on 49 asymptomatic subjects. SNAGs were applied during flexion in sitting at 2 lumbar levels by an experienced examiner in a single session and failed to demonstrate an increase in lumbar ROM measured by a 3-dimensional electrogoniometer. In contrast, the second placebo controlled trial<sup>17</sup> investigated 26 people with LBP during flexion and who were suitable for SNAGs, recording ROM using double inclinometry. A single session of SNAGs demonstrated a significant increase of 7° lumbar flexion ROM greater than placebo, but no change in pain scores. Obviously, in view of the paucity of literature regarding lumbar SNAGs, and in comparison with its widespread clinical use, further investigations are necessary to study lumbar SNAGs' efficacy, as well as indications when used for people with LBP.

Recent studies from our research team<sup>3,19,20</sup> have investigated spine kinematics in people with LBP using an optoelectronic measurement system. A kinematic spine model was developed where the shoulder girdle and spine were divided into 6 segments: shoulder girdle, upper thoracic and lower thoracic spine, upper and lower lumbar spine, and the last segment comprising the whole lumbar spine (combining the upper and lower lumbar spine segments). Each segment was considered to be rigid and homogenous. Kinematic variables speed and ROM were evaluated during movement in all planes. ROM and speed variables showed

a highly significant difference ( $p < 0.001$ ) between healthy subjects and those with chronic non-specific LBP in all spinal segments during flexion and combined movements. These studies provided evidence for the validity of the kinematic spine model in distinguishing people with LBP.

From our previous studies, two new kinematic algorithms ROM (KA-R) and speed (KA-S) were identified as having a potential interest in future clinical studies addressing the effectiveness of OMT interventions applied to the spine in ways other than simply looking at the effects on pain and disability.<sup>19,20</sup> Moreover, it has been proposed that future clinical studies should target their interventions on a more homogeneous subgroup of patients with LBP to improve clinical outcomes, as well as effect sizes for outcome measures.<sup>10</sup>

Based on these findings, we used the kinematic spine model to assess whether lumbar SNAGs were able to improve the kinematic features of trunk movement in a targeted group of subjects with LBP. The main goal of this clinical study was to compare the immediate and short-term effects of a single session of SNAG to a sham SNAG (placebo) treatment applied to the lumbar region, on 2 primary outcome measures, kinematics (KA-R and KA-S), and 3 secondary outcome measures; pain, function, and kinesiophobia in a subgroup of people with LBP. The hypothesis were that outcomes would be more favorable in the real SNAG intervention for primary and secondary outcome measures during between groups analyses, with additional improvements expected within each group over time.

## **Method**

### **Design**

This study was a single-center (Cliniques Universitaires Saint-Luc, Brussels, Belgium), prospective, randomized and placebo-controlled trial with two arms and with blinded patients and evaluator. The design of this clinical trial followed the recommendations of the CONSORT statement.<sup>21</sup> The study was approved by the local ethic committee board of the University of Louvain (UCL) and was registered in ClinicalTrials.gov : NCT02128607.

## Subjects

Eighty-seven people with LBP were initially recruited from “Cliniques Universitaires Saint-Luc”. Of these, thirty-two were included in the study based on specific criteria. Stratification based on pain mechanisms has been previously recommended.<sup>22</sup> These criteria were combined with indications for the application of lumbar SNAGs.<sup>11,12</sup> The inclusion criteria were subjects aged between 20 and 55 years, who complained of LBP mostly provoked by trunk flexion at any stage (acute to chronic), which did not radiate lower than the knee. The subjects were selected where lumbar flexion was the most provocative movement using a standardized physical examination method aimed to identify lumbar pain provocative movement patterns using active and passive accessory movement tests.<sup>23</sup> Finally, the pain associated with trunk flexion had to be reduced by the application of a central lumbar SNAG applied through the spinous process. Patients were excluded if they presented with any known contraindication to OMT (e.g. tumor, fracture, osteoporosis, infection, rheumatic diseases, or herniated disk).

Thirty-two people with LBP were included in the trial and were randomly distributed in two arms: one group receiving the lumbar SNAG treatment (n = 16) and the other receiving a sham lumbar SNAG (n = 16). Randomization was performed by stratified randomization with blocks of random numbers under sealed opaque envelopes previously prepared, in a fashion of 4 subsets, each subset containing 8 envelopes, aimed to balance the stages of LBP for each group during the process of the study.

## Material and outcome measures

The outcome measures were trunk ROM and speed, as well as pain at rest and during trunk flexion just before and just after a single session of treatment. The impact of the intervention at very short-term (2 weeks) on functional disability and kinesiophobia was also evaluated. Six variables were assessed before (T0)

and after treatment (T1) (Figure 1). All the following outcome measures were blindly assessed by the same examiner.

#### Kinematic measures

Kinematic variables were the primary outcome measures and were evaluated using an optoelectronic device (Elite-BTS) composed of eight infrared cameras capable of recording the 3D-positions of 9 reflective markers placed on bony landmarks on the trunk according to a validated kinematic spine model,<sup>19,20</sup> at a frequency of 200 Hz and accuracy of 0.1 mm. This model (Figure 2 A,B) subdivides the shoulder girdle, spine and pelvic girdle into various segments. The test procedure and recording conditions have been described previously.<sup>19,20</sup> Briefly, trunk movements were assessed in a sitting position; trunk flexion, left and right rotation, and combined movement of trunk flexion associated with left and right rotation of the pelvis (Figure 3). Each trunk movement was performed and recorded 10 times.

A binary logistic regression analysis had previously determined segments and trunk movements of the kinematic spine model that were the most discriminant for LBP.<sup>19,20</sup> The final results were two kinematic algorithms, one for ROM (KA-R) and one for speed (KA-S) according to the following equations (see<sup>19,20</sup> for more information):

$$\text{KA-R} = 17.77 - (0.074 \times \text{LTS}^\circ) - (0.11 \times \text{SS}^\circ) - (0.059 \times \text{TLS}^\circ)$$

$$\text{KA-S} = 6.19 - (0.063 \times \text{TLS}^\circ/\text{s})$$

Where KA-R, kinematic algorithm for ROM; LTS<sup>°</sup>, lower thoracic spine ROM in flexion; SS<sup>°</sup>, shoulder segment ROM in right rotation; TLS<sup>°</sup>, total lumbar spine ROM in flexion with left rotation; KA-S, kinematic algorithm for speed; TLS<sup>°</sup>/s, total lumbar spine speed in flexion with right rotation.

### Self-reported measures

Self-reported measures were the secondary outcome measures. Pain at rest (present pain), as well as pain during trunk forward bending from a standing position was recorded using a 10 cm visual analogue scale (VAS) just before and just after the intervention. Functional disability was assessed with the use of the Oswestry Disability Index (ODI) before intervention and 2 weeks after. The score was expressed in percentage terms (%). Kinesiophobia was assessed with the Tampa scale.

### Intervention

First through a standardized clinical examination incorporating combined movements evaluation,<sup>23</sup> the examiner determined if the patient had greater pain during active trunk flexion than extension, as well as the most painful vertebral level (with passive accessory intervertebral movements). This combined movements examination procedure has previously been described and validated to identify the most painful pattern of trunk movement, as well as the lumbar segmental level(s) involved.<sup>23</sup>

Secondly, the evaluator determined whether the patient responded positively to a seated lumbar SNAG applied through the spinous process of the involved vertebra.<sup>13</sup> To do this, the examiner had four attempts to increase ROM and reduce pain by at least 2/10 on the VAS. As recommended,<sup>13</sup> the evaluator applied the SNAG on the spinous process of the vertebra that was the most painful during combined movements examination. Glide force was applied parallel to the apophyseal articular surface (cranial direction). If the effect obtained was not sufficient, the examiner was allowed to vary the intensity and/or direction (vector of applied force) of the SNAG. In addition, the evaluator could change the central vertebral level of lumbar SNAG application.<sup>13</sup> If, after four trials, the SNAG application did not provide the desired effect, the patient was excluded from the study (Figure 1).



In both groups, during the treatment, the patient was placed in a standardized seated position (hips and knees in 90° flexion) on a table with feet supported, stabilized with a belt around the waist (Figure 4).<sup>11,16</sup> Three sets of six repetitions were performed in the Real-SNAG and sham (placebo) intervention. A single inexperienced physiotherapist (novice in the use of SNAGs) applied the treatment procedure in both groups and was therefore not blind to the patient's group allocation. Both the treating therapist and evaluator were trained for 16 hours to ensure correct application of the study protocol by two experienced manual therapists.

In the Real-SNAG group, the therapist followed published guidelines for SNAG application.<sup>11-13</sup> The therapist applied a gliding force with the hypothenar eminence placed on the spinous process of appropriate lumbar vertebral level while the patient performed the limited trunk flexion movement until onset of pain before returning to the starting position (Fig. 4). The cranial glide force was maintained throughout all the movement in both direction (forward bending and back from bending) and with each repetition. Communication was maintained with the patient to ensure that no pain was felt during the treatment.

In the Placebo group, the Sham-SNAG intervention replicated the same procedure used in a previous study.<sup>16</sup> The technique mimicked the Real-SNAG, only with two differences: the therapist placed his hypothenar eminence on the spinous process of the above vertebral level and applied minimal glide force in a caudal direction.

#### Statistical analysis

Statistical analysis was carried out using SigmaStat 3.5. Estimation of the required sample size was calculated on the basis of the Minimal Detectable Change 95% (MDC<sub>95</sub>) of the primary outcome measure (KA-R and KA-S)<sup>20</sup> with a desired power of 0.80 and an alpha level of 0.05; we obtained an estimation of

the required sample size for each group to be 16 patients. Similarity of baseline measures between groups (T0) was assessed using a Student T-test. Our main hypothesis was the comparison between the groups for primary kinematic outcome measures and for self-reported outcome measures. We used Mann-Whitney Rank Sum Test on the means of difference (T0-T1) of the Sham and Real group for statistical evaluation as the majority of the variables failed to demonstrate a normal distribution. We performed a specific alpha correction for inflated type-1 error with null hypothesis rejection using a Bonferonni correction. For primary outcome kinematic measures (KA-R and KA-S), this correction was  $0.05/2$ , indicating  $p < 0.025$  was the required level for significance. For the secondary self-reported measures (VAS rest, VAS flexion, ODI, TAMPA) the correction was  $0.05/4$ , indicating  $p < 0.0125$  was the required level for significance. The clinical effect size for between groups analysis was evaluated with a non-parametric effect size, Cliff's delta.<sup>24</sup> This score can range from -1 to 1; where 1 indicates all observations from the sham-SNAG group are greater than all observations from the real-SNAG group. Conversely, -1 indicates that all observations from the sham-SNAG group are less than all observations from the real-SNAG group. Finally, 0 indicates perfect overlap, with equality of observations between the groups.<sup>24</sup> Cliff's delta is calculated with *R* software and are presented with a confidence interval (CI) of 95% and categorized in small, moderate, large, and very large effect sizes.<sup>24</sup> We also ran an exploratory analysis for the secondary within-group hypothesis (between baseline and final evaluation) in the sham and real-SNAG group following the same statistical method described above but with a Wilcoxon Signed Rank Test.

## Results

The number of patients included and excluded, as well as the reasons of exclusion during the process of the study is reported in Figure 1. Anthropometric data and variable outcomes at baseline of included patients are described in Table 1. The period of participants enrollment was from February 2014 until June

2014, the end of follow-up was July 2014. The trial was ended in July 2014 because the required sample size was reached.

Subjects with non-specific LBP included in this study had a mixed pain history: 63% were chronic, 21% acute, and 16% subacute. No significant differences on outcome measures were present at baseline between groups (Table 1). No serious or moderate adverse events were reported in either group during the study.

The graph of speed curves ( $^{\circ}/s$ ) of the lower lumbar spine segment during trunk forward bending in one typical acute LBP patient and one typical chronic LBP patient from the Real-SNAG (Figure 5A) and Sham-SNAG (Figure 5B) group is presented in figure 5.

#### Between groups comparison

##### Primary kinematic outcome measures

KA-R demonstrated a significant difference ( $p < .025$ ) in favor of the Real-SNAG group with large clinical effect size ( $p = .014$  and  $ES = -.52$ ). In contrast, KA-S demonstrated no significant difference ( $p > .025$ ) with only small clinical effect size ( $p = .118$  and  $ES = -.33$ ).

##### Secondary self-reported outcome measures

Pain (VAS) at rest and during lumbar spine flexion demonstrated a significant difference ( $p < .0125$ ) in favor of the Real-SNAG group with large clinical effect size ( $p = .001$  and  $ES = -.73; -.75$ ). Functional disability (ODI) also demonstrated a significant difference ( $p < .0125$ ) in favor of the Real-SNAG group with large clinical effect size ( $p = .003$  and  $ES = -.61$ ). In contrast, there was no significant difference between groups for Kinesiophobia (Tampa scale) ( $p > .0125$ ), with only a moderate clinical effect size favoring the real-SNAG group ( $p = .03$  and  $ES = -.46$ ).

Within group comparison (secondary explanatory hypothesis)

Primary kinematic outcome measures

KA-R and KA-S before and after the intervention improved significantly in the Real-SNAG group (respectively:  $p=.001$ ;  $p=.008$ ) but not in the Sham-SNAG group (respectively:  $p=.86$ ;  $p=.63$ ).

Secondary self-reported outcome measures

There were significant improvements in the real-SNAG group for all secondary outcome measures following the intervention. Pain (VAS) at rest and during lumbar spine flexion before and after intervention improved significantly in the Real-SNAG group ( $p<.001$ ) but not in the Sham-SNAG group (respectively  $p=.56$ ;  $p=.15$ ). Functional disability (ODI) before and 2-weeks after the intervention improved significantly in the Real-SNAG group ( $p=.002$ ) but not in the Sham-SNAG group ( $p=.84$ ). Kinesiophobia (Tampa scale) before and 2-weeks after the intervention improved significantly in the Real-SNAG group ( $p=.004$ ) but not in the Sham-SNAG group ( $p=.23$ ).

## **Discussion**

Our results suggest substantial improvements favoring lumbar SNAG's as compared to placebo for KA-R, pain at rest and during trunk flexion, as well as for functional disability. In contrast, KA-S and kinesiophobia showed no significant difference between groups. Despite this, within group explanatory analysis demonstrated highly significant differences in all outcome measures before and after intervention only in the real-SNAG group.

It may be hypothesized that a larger sample size may have resulted in significant differences between groups for KA-S also. However, our prospective calculation

of sample size provided an estimate of 16 patients within each group for kinematic outcome measures. With such a small sample, the statistical effect of possible atypical responses is greater. Indeed, almost all patients from our sample (80%) improved their speed (KA-S) in both groups after the intervention. However, a small percentage (20%) of subjects demonstrated the opposite response, and decreased speed during trunk-movements after lumbar real and sham SNAG therapy. Moreover, the mix of different stages of LBP included in our sample, from acute to chronic, is another factor that may explain the observed non significant between groups effect on KA-S.

When comparing the current results to previous studies reporting on the effects of Mulligan techniques, most of them have investigated the effects of MWM on peripheral joints<sup>25-30</sup> or on the cervical spine.<sup>31-33</sup> However, there are few published reports investigating effects with respect to the lumbar spine. Indeed, only two studies have addressed the effects of lumbar SNAGs on ROM and pain. The first study,<sup>16</sup> a placebo controlled trial, showed no-significant improvement in active trunk flexion ROM after lumbar SNAGs in asymptomatic people. However, it is problematic to compare those results in asymptomatic people (where the SNAG technique could not be applied according to the technique guidelines<sup>11-13</sup>) with the present study on people with LBP. The second study,<sup>17</sup> investigated patients with LBP and showed a significant increase in trunk flexion ROM, but no significant reduction in pain after the application of lumbar SNAGs. Our results show that lumbar SNAGs reduced pain at both rest and during active trunk flexion, and also increased trunk ROM. The effectiveness of SNAGs was not limited to just pain reduction and improved ROM, but also to improved functional disability and kinesiophobia in people with LBP. However, long-term effects were not analyzed in this study. It would be interesting to analyze long-term effects of lumbar SNAGs in future studies.

In the study of Konstantinou et al.,<sup>17</sup> the placebo was a passive modality (patient lying on the table). The authors made this choice in order to avoid the influence of an active placebo on the quality of trunk movement probably because

repeated active spinal movements could be considered as a self-treatment for LBP.<sup>34,35</sup> However, the authors could not distinguish the possibility that patients in the SNAG group have improved only through repetition of movements rather than SNAG technique application. Moreover, an active placebo as in our study mimicked as closely as possible a real treatment. In our protocol, the same total number of active trunk movements was performed in both groups, in order to distinguish the effect of real and sham SNAGs from the simple effect of repeated active trunk movements.

The exact mechanism of potential action for lumbar SNAGs is not known as no studies have yet investigated this. However, there are proposed biomechanical and neurophysiological mechanisms. Biomechanically, there are some similarities between postero-anterior mobilization (PA) undertaken in prone lying and a SNAG. Lee and Evans<sup>36</sup> reported that a PA on the L5 spinous process induced anterior translation of the L5 vertebra and flexion at the L5-S1 segment. The biomechanical effects of a lumbar SNAG may be enhanced by the cranial direction of the glide along the facet joint plane, together with the active trunk movement. Another proposed mechanism of action may be through correction of a positional fault. Mulligan hypothesized that lack of normal facet gliding in flexion may distort the disc<sup>11,12</sup> and provoke pain. Hence improving facet gliding may normalize forces on the disc, relieving pain.

Zusman<sup>37,38</sup> has described a rationale for the pain relief provided by manual therapy based on the theory of extinction and habituation. Pain may be considered as a form of aversive memory that once present could be more and more easily recalled. Behaviorally, a conditioned fear response may be reduced in intensity through extinction, a form of learning characterized by a decrease in a conditioned response when the conditioned stimulus that elicits it is repeatedly non-reinforced<sup>37,38</sup> such as might occur during SNAGs. In our sample of people with LBP, trunk flexion was the most painful movement. The real SNAG intervention provided exposure to the painful movement in the absence of any overt danger, which is fundamental to interventions used in the extinction of aversive memories,<sup>37,38</sup> but this was not the case for the sham SNAG intervention. Progressive mobilization may also desensitize the nervous system

through habituation. The mechanism involves a progressive decline in the ability of the presynaptic nerve terminal to transmit impulses. In the subjects from this study, non-noxious sensory input from the repeated real lumbar SNAG may have competed with and replaced pain sensitization, returning the nervous system to a normal state.<sup>38</sup>

There may be various mechanisms of action for lumbar SNAGs at different stages of LBP. In our sample there was a mix of stages, with the majority being chronic in nature. As we have discussed, SNAGs may have neurophysiological as well as mechanical effects, which may have implications for acute and chronic LBP. However, it is beyond the scope of this study to identify the mechanisms underscoring the positive changes seen from SNAGs.

These proposed mechanisms of action described here might explain the significant difference observed on outcome measures in favor of real SNAG interventions. However, for Kinesiophobia there was no significant difference for between groups analysis after Bonferonni correction despite significant improvement in the real-SNAG group for within group analysis. This might be explained by the nature of the sham intervention in which the subjects were still exposed to the painful stimulus during trunk flexion, and thus, may maintain a conditioned fear response. Moreover, another often debated issue is the quality of the placebo procedure used in physical therapy trials because that might explain the results in favor of the real intervention. Placebo in manual therapy and in non-pharmacological trials is still a very complex issue to address since a good quality placebo needs to mimic as closely as possible the real intervention without its specific effect with patients still believing that they have received the real treatment.<sup>10</sup>

There are several potential limitations to this study's findings. One is the limited clinical experience of the treating therapist in the use of SNAGs that may have influenced the effectiveness of the intervention.<sup>39,40</sup> However, SNAGs are simple techniques that require minimal training, so this is not believed to be a substantial factor in the outcome of the technique. Moreover, some caution is required when interpreting the outcome measures in favor of the real SNAG

group, as the 95% CI covers a wide range of possibilities in terms of effect size. Finally, a potential bias could be present during the initial selection of patients as they were required to respond positively to the SNAG application, before inclusion and randomization to one of the groups. This procedure may have the potential to subconsciously inform the patients of the real SNAG effects during the selection. However, this procedure is consistent with the widespread recommendations of stratification of care for LBP patients,<sup>10,22</sup> as well as the integration of the clinical reasoning in manual therapy trials.<sup>10,15,22,37,39</sup>

To corroborate the positive changes of lumbar SNAGs seen in this study, future studies should further investigate the effects on speed of trunk-movements and kinesiophobia, long-term efficacy, and possible mechanisms of action. Moreover, correlations between primary kinematic outcomes measures and secondary clinical outcome measures should be investigated. Finally, more studies are required to identify potential responders to validate the clinical application of this form of manual therapy.

## **Conclusion**

This is the first randomized placebo controlled trial that has investigated the short-term effects of lumbar SNAGs on two new kinematic algorithms of trunk movements (KA-R and KA-S), as well as pain, functional disability and kinesiophobia in patients with non-specific LBP. While the results show a significant improvement in KA-R, pain, and functional disability in favor of lumbar SNAGs, some caution is required when interpreting these data, as the 95% CI covers a wide range of possibilities in terms of clinical effect size. Hence this study provides preliminary evidence that lumbar SNAGs have immediate and short-term efficacy in the treatment of a targeted group of patients with non-specific LBP.

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**Table 1. Anthropometric data and outcome variables at baseline**

	<b>Sham-SNAG (n=16)</b>	<b>Real-SNAG (n=16)</b>
Male / Female	7/9	9/7
	Means (SD)	Means (SD)
Age (years)	40.7 (10.2) <sup>NS</sup>	37.8 (9.7)
BMI (kg/m <sup>2</sup> )	25.1 (3.3) <sup>NS</sup>	24.1 (2.6)
LBP duration (months)	19.7 (19.4) <sup>NS</sup>	21.0 (21.2)
KA-R (T0)	3.5 (2.9) <sup>NS</sup>	4.9 (3.2)
KA-S (T0)	2.1 (1.4) <sup>NS</sup>	2.4 (1.9)
VAS at rest (present pain) T0	2.5 (1.7) <sup>NS</sup>	3.0 (1.8)
VAS flexion (pain in trunk flexion) T0	5.1 (1.6) <sup>NS</sup>	5.6 (1.8)
ODI (T0)	22.9 (10.7) <sup>NS</sup>	22.4 (12.2)
Tampa scale (T0)	42.1 (6.2) <sup>NS</sup>	43.7 (6.3)

BMI: body mass index; KA-R: kinematic algorithm for range of motion; KA-S: kinematic algorithm for speed; T0 : baseline ; VAS : visual analogue 10 cm scale ; ODI : Oswestry disability index ; NS : non-significant difference between groups with Student T-test.

**Table 2: Between groups analysis on primary kinematic and secondary self-reported outcome measures**

Outcome measures	Sham-SNAG (n=16) Median (interquartile range)	Real-SNAG (n=16) Median (interquartile range)	<i>p-value</i>	Effect size (Cliff's Delta) with confidence interval (CI95%)
KA-R	0.05 (-0.73 : 0.59)	-0.88 (-2.91 : -0.44)	.014*	-.52 (-.77 : -.12)
KA-S	-0.05 (-0.88 : 0.63)	-0.65 (-1.45 : -0.03)	.118	-.33 (-.65 : .09)
VAS rest	0 (0 : 0.5)	-1 (-2 : -1)	<.001#	-.73 (-.91 : -.35)
VAS flexion	0 (-1.5 : 0)	-3 (-3 : -1.5)	<.001#	-.75 (-.90 : -.44)
ODI	0 (-2 : 2)	-5 (-8 : -1)	.003#	-.61 (-.83 : -.23)
TAMPA	0 (-2 : 1)	-6 (-9.5 : -0.5)	.03	-.46 (-.76 : .01)

KA-R: kinematic algorithm for range of motion. KA-S: kinematic algorithm for speed. VAS rest: visual analogue scale (pain) at rest. VAS flexion: visual analogue scale (pain) during trunk flexion. ODI: Oswestry Disability Index (functional disability). TAMPA: TAMPA scale for kinesiophobia. \* Significant difference between baseline and final evaluation within groups, corrected level of  $p < 0.025$  for primary kinematic outcome measures (KA-R and KA-S). # Significant difference between baseline and final evaluation, corrected level of  $p < 0.0125$  for secondary self-reported outcome measures.

**Table 3: Within group analysis before and after treatment**

Outcome measures	Sham-SNAG (n=16)			Real-SNAG (n=16)		
	Median (interquartile range) at T0	Median (interquartile range) at T1	<i>P-value</i>	Median (interquartile range) at T0	Median (interquartile range) at T1	<i>P-value</i>
KA-R	3.28 (1.36-6.41)	3.69 (0.82 : 5.81)	.86	4.85 (2.56 : 7.23)	2.44 (-0.57 : 5.32)	.001*
KA-S	2.27 (0.65-3.42)	1.68 (0.87 : 2.72)	.63	2.59 (0.66 : 4.14)	1.09 (-0.12 : 2.63)	.008*
VAS rest	2 (1.5-3.5)	2 (1.5 : 4)	.56	3 (1 : 4)	1.5 (0.5 : 3)	<.001#
VAS flexion	5 (4-6)	4 (3-5 : 5)	.16	5.5 (4 : 6.5)	3 (2 : 4)	<.001#
ODI	20 (16-27)	20 (17 : 27)	.84	21 (13 : 34)	14 (12 : 25)	.002#
TAMPA	41 (38-45)	41.5 (36.5 : 45)	.23	44 (40 : 50)	38.5 (34.5 : 42.5)	.004#

KA-R: kinematic algorithm for range of motion. KA-S: kinematic algorithm for speed. VAS rest: visual analogue scale (pain) at rest. VAS flexion: visual analogue scale (pain) during trunk flexion. ODI: Oswestry Disability Index (functional disability). TAMPA: TAMPA scale for kinesiophobia. \* Significant difference between baseline and final evaluation within groups, corrected level of  $p < 0.025$  for primary kinematic outcome measures (KA-R and KA-S). # Significant between baseline and final evaluation, corrected level of  $p < 0.0125$  for secondary self-reported outcome measures.

**Figure caption list**

Figure 1. Flow chart of the study process

Figure 2 (A): Position of the patient and the nine reflective markers, (B): kinematic spine model and segments: pelvic girdle (ASIS L-S2-ASIS R); low lumbar spine (S2-L3); high lumbar spine (L3-T12); total lumbar spine (S2-T12); low thoracic spine (T12-T7); high thoracic spine (T7-C7); shoulder girdle (Ac L-C7-Ac R)

Figure 3: (A) starting position and trunk flexion, (B) starting position and Left / Right rotation, (C) starting position and combined movement of trunk flexion with pelvic rotation to the left / right.

Figure 4. Standardized position of the patient and therapist showing the belt placement during the application of the real and sham lumbar SNAG during trunk movement in flexion

Figure 5A: Speed curves of the lower lumbar spine segment (S2-L3) during trunk forward bending before (baseline) and after (final evaluation) Real-SNAG for one typical (best responder) acute LBP patient (red curve) and one typical chronic LBP patient.

Figure 5B: Speed curves of the lower lumbar spine segment (S2-L3) during trunk forward bending before (baseline) and after (final evaluation) Sham-SNAG for one typical (best non-responder) acute LBP patient (red curve) and one typical chronic LBP patient.