

INNOVATIVE PAIN MANAGEMENT DEVICE USING MILLIMETRE BAND RADIATION : ELECTRONIC-PAIN KILLER. ASSESSMENT IN PATIENTS WITH PERIPHERAL OSTEOARTHRITIS. MONOCENTRIC, PROSPECTIVE, RANDOMISED IN CROSS-OVER DESIGN AND CONTROLLED TRIAL



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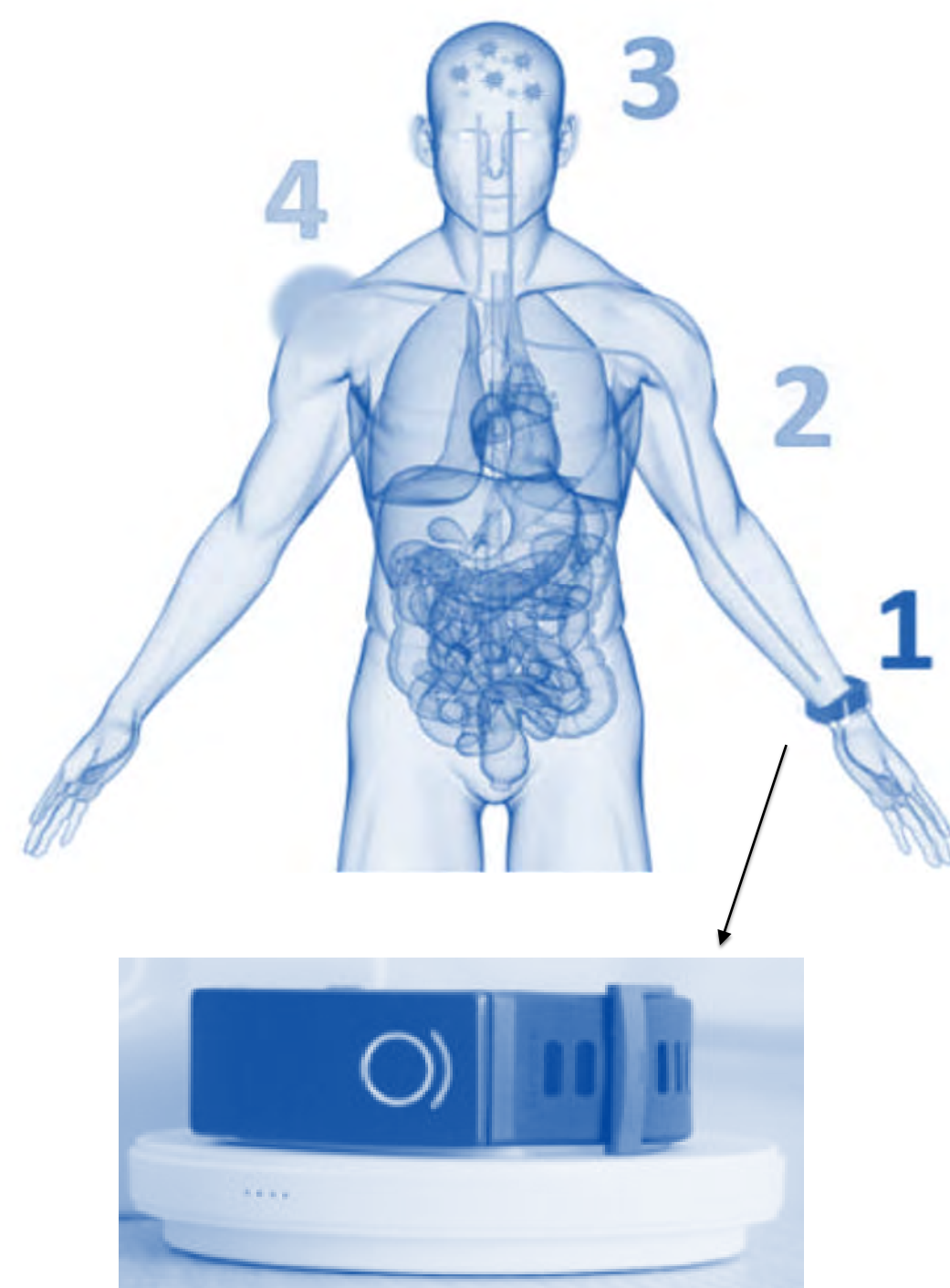
BACKGROUND AND OBJECTIVES

Osteoarthritis (OA) is one of the most common chronic health conditions affecting more than 500 million people worldwide. Combination of non-pharmacological and pharmacological treatments are recommended to manage patient's pain [1]. The results of the French online survey "Stop OA" showed the lack of resources to propose new therapeutic strategies to improve pain management for patients [2]. Our objective was to assess an **innovative medical device (MD)** for neuromodulation of pain in patients with peripheral OA. In this way, a clinical trial was conducted to evaluate if the regular use of this MD would reduce the pain felt by the patients (primary outcome) and if it would improve their quality of life and sleep (secondary outcomes).

PAIN MANAGEMENT DEVICE

"Low-power millimetre wave transmitter wristband"

Waves application on a highly innervated skin area, at the inner part of the wrist (1), has neuromodulatory effects (2) thanks to the synthesis and release of endorphins (3) and parasympathetic system activation providing rapid and natural pain relief (4).



TRIAL DESIGN



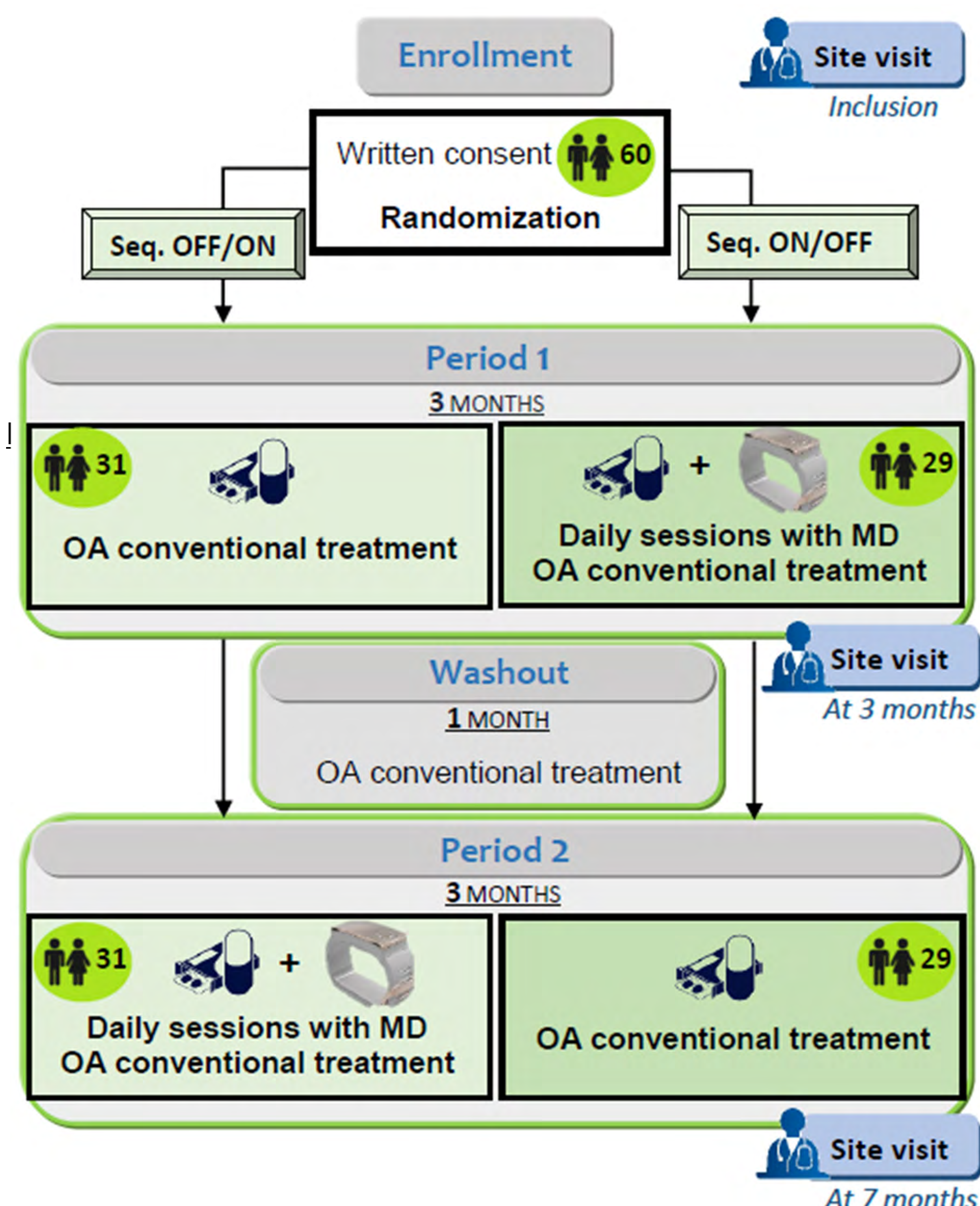
Patients were followed in the University Hospital of Grenoble Alps (France) with a **peripheral OA** and a **pain score ≥ 4** on the Visual Analogic Scale (VAS)



Randomization 1:1 in one of the two cross-over sequences with stratification on the most painful OA localisation (upper or lower limbs (Figure 1))



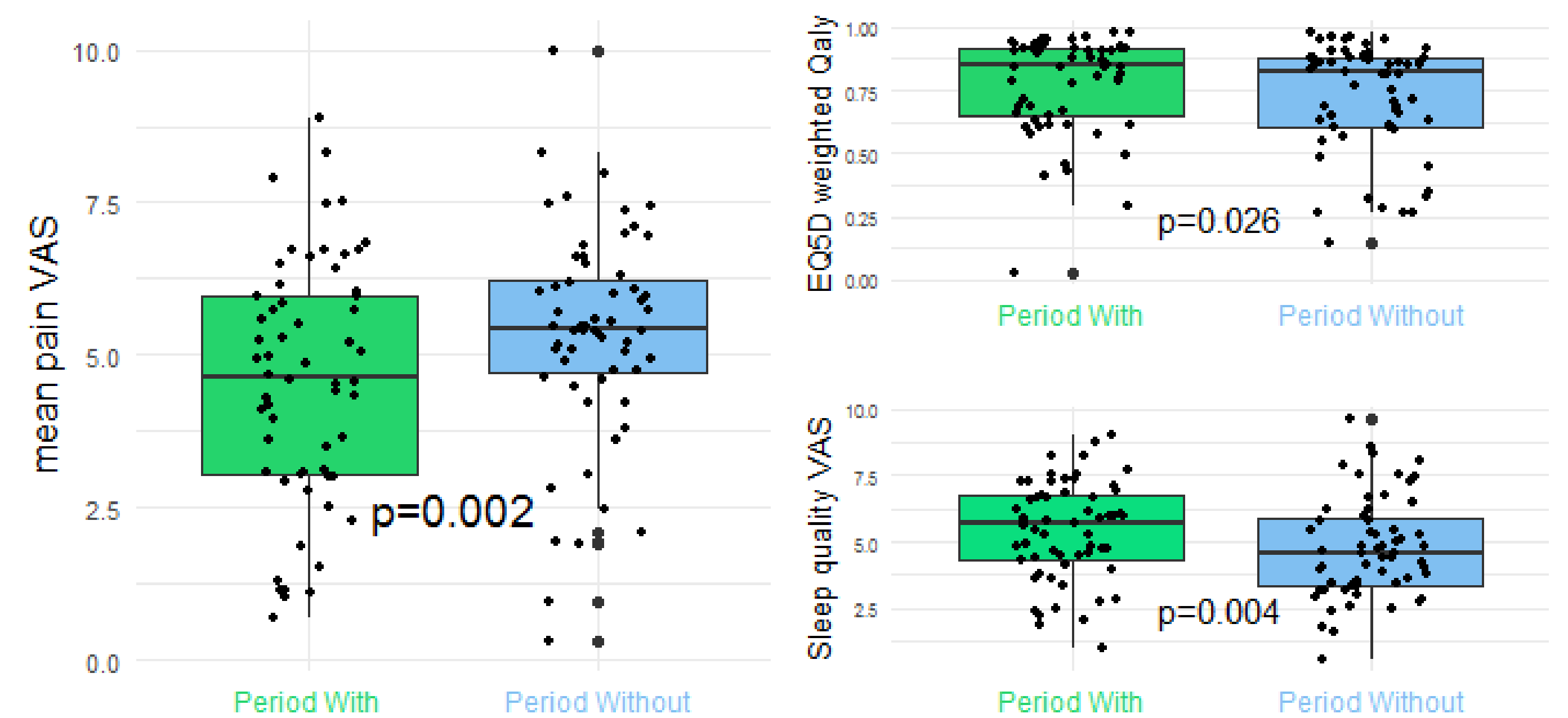
MD use instructions : 1 to 3 sessions/day with the wristband. Duration of each session : 40 minutes



RESULTS

Figure 2 : Pain VAS, EQ5D-5L and sleep quality VAS

Analyses were performed in intention to treat. $p < 0.05$ was considered significant.



RESULTS (Median[IQR])			
		With MD	Without MD
Primary outcome	Pain VAS	4.6 [3.1 ; 6.0]	5.4 [4.7 ; 6.2]
Secondary outcomes	EQ5D-5L	0.85 [0.65 ; 0.92]	0.82 [0.61 ; 0.88]
	Sleep quality VAS	5.7 [4.4 ; 6.8]	4.6 [3.4 ; 5.9]

- No severe adverse event related to MD use was observed
- Linear mixed effect model for repeated VAS measurements :
 - No carryover and no sequence effect
 - No effect from unbalanced factors at baseline and stratification factor

Figure 3 : Baseline characteristics of the intention-to-treat population

	Total = 60 patients	Age : 65.8 \pm 7.2 years old Pain VAS : 6.2 \pm 1.4 (Mean \pm SD)
Sequences were comparable regarding all variables except:		
	Sex ratio	Body mass index
Sequence OFF/ON	5 Males / 5:26	24.3 \pm 4.0 (kg/m ²)
Sequence ON/OFF	1 Male / 1:28	27.8 \pm 4.7 (kg/m ²)

CONCLUSION - PERSPECTIVES

In this academic study, we showed that regular exposure to this new MD could, non pharmaceutical therapy opens a new lead to significant reduction in pain (VAS), improve quality of life (EQ5D-5L) and sleep quality (VAS) in patients with peripheral OA.

Easy to use and safe, this innovative field for OA pain management with the benefit of being ambulatory, non invasive and self-managed.

Given the high variability of these results and because pain is ultimately subjective, future research should focus on individualized benefit-risk balance evaluation with sensible patients preferences elicitation. We are currently working on such analyses which are urgently needed to bridge the gap between evidence-based medicine and patient-centered care, allowing for more precise patient responsiveness evaluation.