

Cover Letter

Dear,

The study “**Reflex therapy of temporomandibular dysfunctions – randomized controlled pilot study**”, registered with ISRCTN under the number **ISRCTN17648638**, has been completed. The study results **have not yet been published in a peer-reviewed scientific journal**.

In accordance with ISRCTN requirements, we are therefore submitting a basic summary of the study results, including participant flow, baseline characteristics, outcome measures, and information on adverse events. The data are presented descriptively only, without interpretation.

Kind regards,

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Basic Summary of Study Results

1. Participant Flow

A total of **40 participants** were assessed and enrolled in the study. All participants were randomized in a 1:1 ratio. Twenty participants were allocated to the control group and 20 participants to the experimental group. All participants received the allocated intervention and were included in the final analysis. No participants were lost to follow-up and no participants were excluded from the analysis.

- Assessed for eligibility: **n = 40**
- Randomized: **n = 40**
- Control group – standard rehabilitation: **n = 20**
- Experimental group – standard rehabilitation + reflex therapy/dry needling: **n = 20**
- Lost to follow-up: **n = 0**
- Included in the final analysis: **n = 40**

2. Baseline Characteristics

A total of **40 patients, 30 women and 10 men**, aged 18–65 years, were enrolled. The mean age of the total study sample was 35.2 ± 8.4 years. The control group included 20 participants and the experimental group included 20 participants.

Characteristic	Control group (n = 20)	Experimental group (n = 20)
Age, mean $\pm$ SD	36.9 ± 8.4 years	33.6 ± 8.3 years
Women	15	15
Men	5	5

Characteristic	Control group (n = 20)	Experimental group (n = 20)
VAS T0, median	6.0	5.0
OHIP-14 T0, median	28.0	24.0

3. Outcome Measures

Primary and secondary outcome measures were assessed at baseline (T0), after the first intervention (T1), and at the end of the programme (T2). Pain intensity was assessed using the VAS, and quality of life was assessed using the OHIP-14.

Outcome measure	Group	T0	T1	T2
VAS (0–10), median	Control	6.0	5.0	3.0
VAS (0–10), median	Experimental	5.0	4.0	2.5
OHIP-14 (0–56), median	Control	28.0	27.0	18.0
OHIP-14 (0–56), median	Experimental	24.0	20.0	15.5

4. Harms / Adverse Events

The submitted manuscript and dataset do not contain a separate record of adverse events. If no adverse events occurred during the study, the following statement may be used:

“No adverse events were associated with this study.”

Flow Diagram

Reflex therapy of temporomandibular dysfunctions

