INFLUENCE OF SILICON BASED TEXTILE FABRICS ON BACK PAIN, BIOMARKER, SLEEP & LIFE QUALITY – FIBRILIUM STUDY PART 1

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A randomized, controlled, double-blinded trial with 48 patients

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INTRODUCTION

Fibrilium is an artificially made fiber that contains silicon crystals from traditional South Korean healing earth as a material component. These crystals are to reflect the natural radiation of the body (especially between 4-14nm wavelength = infrared range) and thereby may have supportive healing and pain relief properties. The assumption is supported by the feedback of various individual users cases. Fibrilium is used particularly for textile fabrics like mattress pads and clothing, which are approved throughout Europe as medical device class 1 (CE certified) for the treatment of pain. These products have been on the market for several years, but they have never been evaluated in a clinical trial. In the present project, which have been approved the ethics committee of Carinthia, the material effects on the human organism, especially when used as a mattress pad, are to be investigated.

RESEARCH QUESTION

Are there any pain reducing effects by using Fibrilium containing mattress pads?

METHODS

Patients have been informed via social media about the opportunity to participate in the study and have been recruited in the private practice of an experienced sports physician (informed consent).

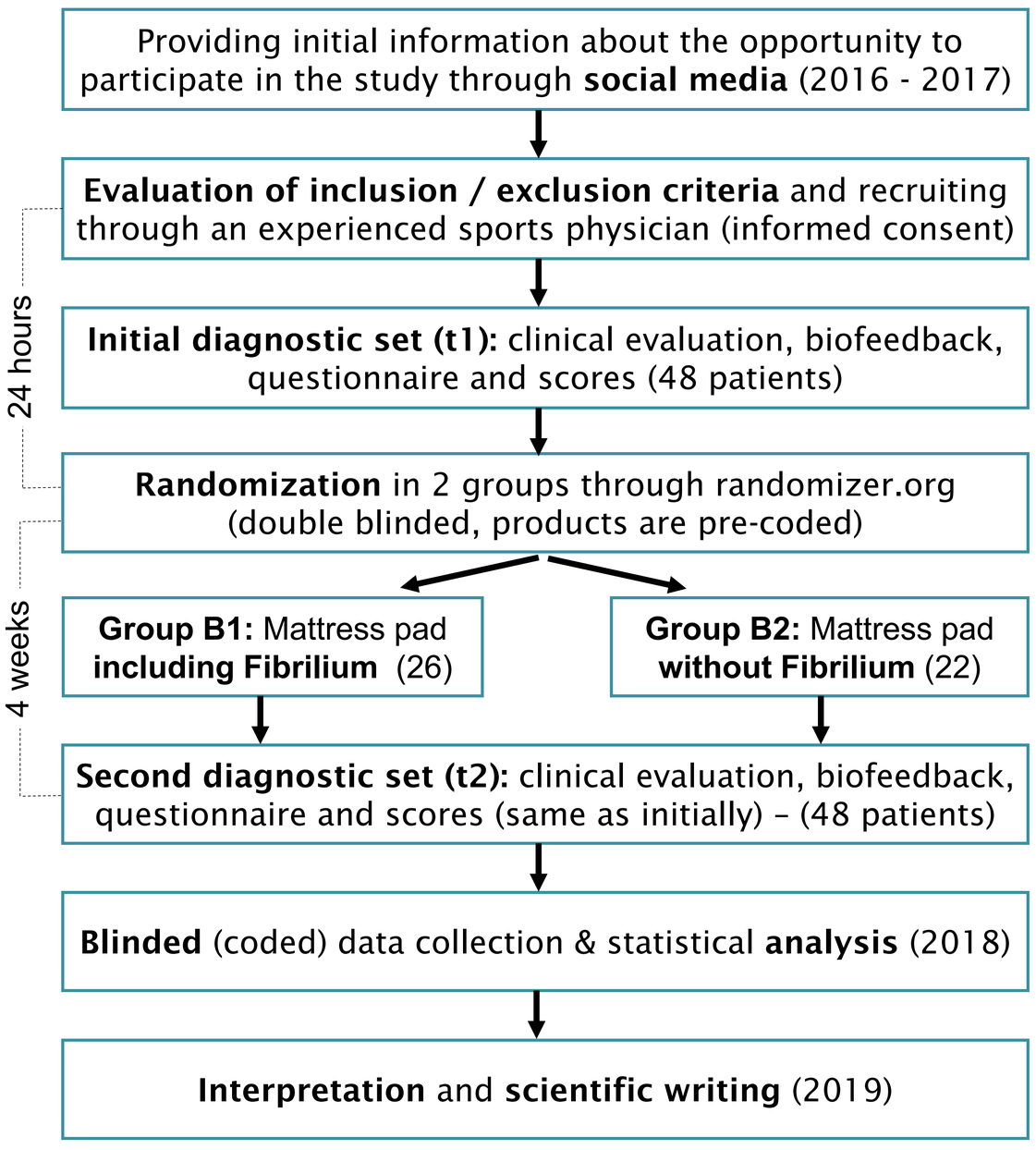

Image 1 – Flow Chart of the clinical trial

Forty-eight patients have been included in the trial and have been given a unique ID after meeting the following criteria. Inclusion: Chronic back pain ≥ 6 weeks, actual minimum pain level 6 of 10, age between 18 and 60 years. Exclusion: Previous spinal operations, acute indication for any spinal operation, body mass index over 35 or chronic psychiatric disorders. The following diagnostic scheme have been carried out at the practice location: General anamnestic and clinical evaluation, biofeedback (heart rate, breathing frequency, skin conductance level = SCL), questionnaire and scores for pain and life quality (SF-36, Pittsburgh Sleep Quality Index, Short Form McGill Questionnaire, Oswestry Low Back Pain Disability Index, Linton & Hallden Score). After this first evaluation set (t1) the study participants have been randomized in 2 groups by using the online tool randomizer.org and each participant have been given a mattress pad to put it between their standard mattress at home and a thin bed sheet to sleep on it for the next 4 weeks from tomorrow. Group B1 have been given a mattress pad incl. Fibrilium fibers, group B2 have been given a mattress pad without Fibrilium fibers. Both types of mattress pads have been visually identical and could have not been distinguished by any other sense. Neither the patient nor the doctor knew which edition have been handed out. The two editions have been identifiable only by a coded number and the key have been available to the study coordinator only. After 4 weeks of sleeping on the mattress pad the patients have been invited to visit the practice for re-evaluation of their conditions with the same diagnostic test set as mentioned above (t2). Data was collected with Google Forms and MS Excel. Data analysis and statistical testing were performed with Statistica v8 by a blinded analyst (coded data).

RESULTS

Residuals were inspected for normal distribution. There were no significant differences of the groups in sociodemographic variables nor in score results at t1. Group B1 / B2: age 46,8 / 44,3 years; female participants 57% / 55%; duration of pain 10,1 / 9,0 years; relationship with doctor 2,1 / 2,2 (good); expectation of therapy 5,7 / 5,8 (average). The statistical tests for evaluating the treatment at t2 were highly significant for the pain variables / scores incl. pain induced disability in the multivariate model:

Variable	Group B1	Group B2	Univariate p
McGill Total Score	8,46 (3,26-9,66)	16,18 (12,94-19,42)	.00003
Oswestry Disability Index	15,23 (7,86-22,60)	28,91 (22,63-35,18)	.0004
Linton-Hallgren Score	56,23 (41,50-70-96)	83,54 (73,85-93,24)	.000009

Table 1 – Weighted means from multivariate analysis of covariance of the pain scores (95% confidence intervals) at follow-up with baseline score as covariate and univariate tests

Sleep as measured by the Pittsburgh Quality of Sleep Instrument was clearly and significantly better in group B1 ($p \leq 0.0001$). Same is true for all variables of the SF-36 quality of life instrument incl. physical function, role limitation, social functioning, energy level, general health and well-being ($p \leq 0.01$). Variables for pain severity (3,15 / 6,23) and general feeling (7,61 / 5,23) at t2 were also significantly better in group B1 vs. group B2, respectively. Biofeedback data showed significant reduction of heart rate (68 / 74 bpm $p \leq 0.05$) for group B1, reduction of breathing frequency in women for group B1 (14,8 / 18,0 pm $p \leq 0.05$) and reduction of SCL ($p \leq 0.01$) at t2.

CONCLUSION

The evaluation of the data of this study yields a clear picture. Group B1 reported less pain, had less disability, reported better quality of sleep and better quality of life than group B2. Effect sizes range between eta2 = 0.39 and 0.45 and are thus to be considered large. Considering the fact that the average duration of back pain was about ten years the results can be seen as very promising, as they were not only statistically highly significant, but also clinically relevant. Further trials are necessary to investigate the pathophysiological mechanisms of these effects and to evaluate other possible applications of the therapy.