

## Effectiveness of App-based relaxation for patients with chronic low back pain (Relaxback) - a pragmatic randomized trial

### Summary:

With a lifetime prevalence of 80%, patients with low back pain are the largest group among patients with chronic pain causing high socio-economic costs. The German treatment guideline for "low back pain" recommends relaxation techniques such as progressive muscle relaxation as part of a multi-modal treatment strategy against chronic low back pain. Moreover, relaxation techniques, such as autogenic training, guided imagery, and mindfulness therapies are used for the treatment of chronic pain. At present, the effect of additional self-practice on chronic low back pain in a usual care setting is unclear.

The aim of this pragmatic randomized study is to evaluate whether relaxation techniques in addition to usual care prove more effective in the reduction of chronic low back pain compared to usual care alone. 220 patients aged 18-65 years with chronic (>12 weeks) low back pain and a mean pain score  $\geq 4$  on a Numeric Rating Scale (NRS) in the last week before randomization will participate in the study.

Participants will be randomized in two groups (relaxation exercise, usual care alone as waiting list). Participants in the intervention group will apply a 15-minute relaxation exercise guided by a smartphone application ("app"). The exercise should be applied daily, (minimally, five days per week) for 6 months. The app contains audios to guide autogenic training, mindfulness based training and guided imagery. On a daily basis, participants can select one of the three exercises which they want to apply.

At baseline, all participants will complete a paper-and-pencil outcome measure. After 3 and 6 months, participants will complete an app-based electronic questionnaire regarding outcome measures. Participants will fill-out a weekly diary and also answer a daily question on their low back pain intensity. Both the low back pain question and the diary will be provided via the app.

The primary outcome is the mean pain intensity after 3 months measured by the daily pain intensity on the NRS. Secondary outcome parameters are the mean pain intensity measured weekly as the average pain intensity of the last seven days on a NRS, pain acceptance (German version of Chronic Pain Acceptance Questionnaire), stress (NRS), sick leave days, and pain medication intake.

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