Digital Acceptance and Commitment Therapy for the Treatment of Chronic Pain

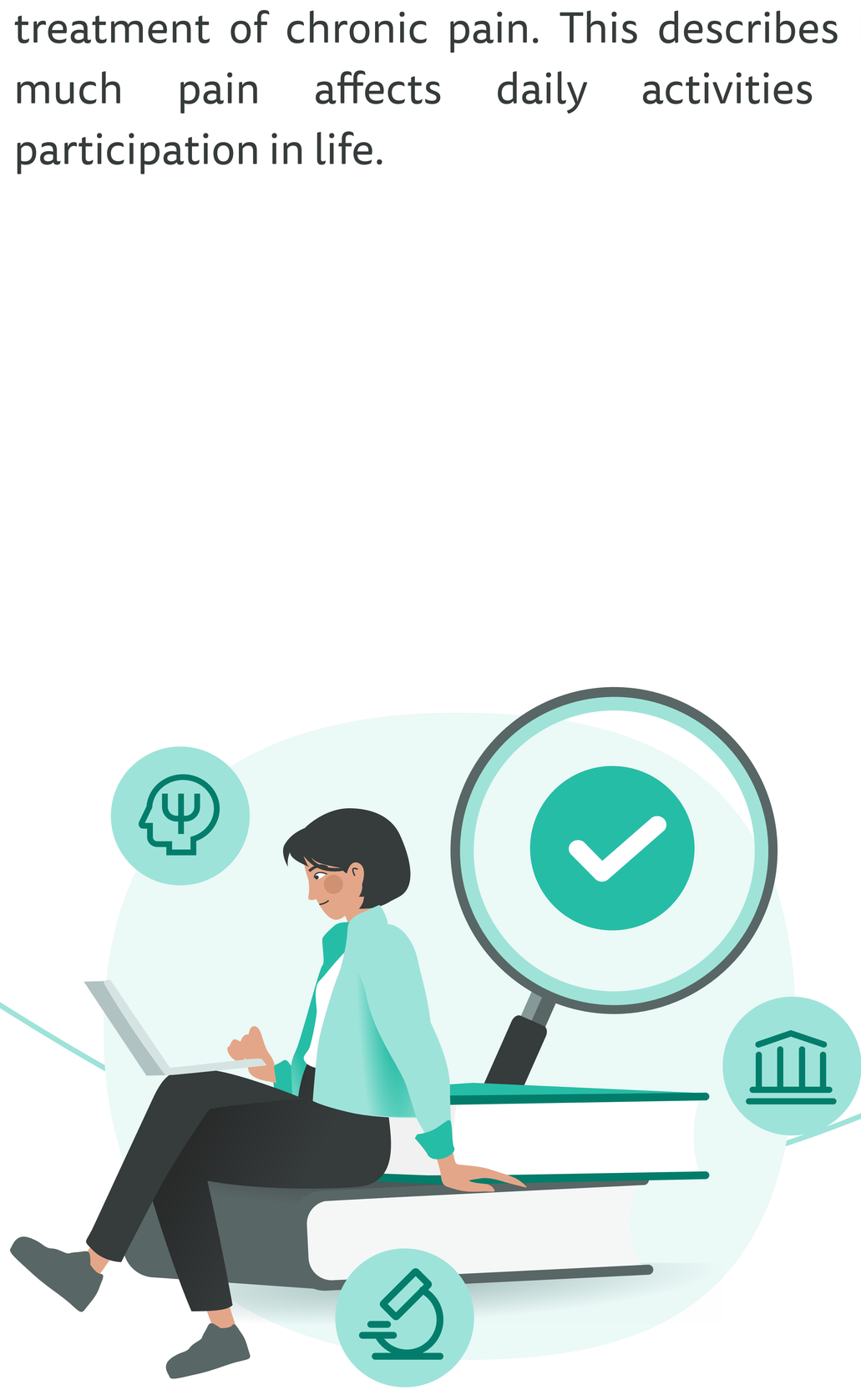
Summary of the Efficacy Study

Acceptance and Commitment Therapy (ACT) has established itself as an effective augmentation of Cognitive Behavioural Therapy (CBT) for the treatment of chronic pain. Despite the high prevalence of chronic pain, which is associated with functional impairment and emotional distress, those affected face limited access to established psychotherapeutic services.

As an ACT-based online therapy programme, the digital health application (DiGA) HelloBetter Chronic Pain offers a guideline-compliant multimodal pain therapy for people with chronic pain.

In 7 interactive units, patients learn principles and strategies of acceptance, mindfulness, and value work. Thus, patients are encouraged to pursue an active and conscious lifestyle as well as personal values and goals. Through this approach, pain interference can be reduced and emotional functionality enhanced.

With the reduction of pain interference, the DiGA addresses a central therapeutic goal in the treatment of chronic pain. This describes how much pain affects daily activities and participation in life.



HelloBetter

Results of the Efficacy Study

During the regulatory approval process as a DiGA, the efficacy of HelloBetter Chronic Pain has been evaluated in a randomised controlled trial. The study was registered in the German Clinical Trials Register (DRKS): DRKS00027176[1].

Participants in the intervention group were given access to the online therapy programme HelloBetter Chronic Pain. The participants in the control group were offered free access to the DiGA after 12 weeks, upon request. Both of the study groups had unrestricted access to all standard care measures equivalent to treatment-as-usual (TAU).

The study included *N* = 360 adults with chronic pain (duration > 3 months), substantial pain interference, and one of the following ICD-10 diagnoses: fibromyalgia (M79.7), back pain (M54), persistent somatoform pain disorder (F45.40), chronic pain disorder with somatic and psychological factors (F45.41), chronic intractable pain (R52.1), and other chronic pain (R52.2). The average age of the participants was 49.17 years (*SD* = 11.56), and the majority of them were female (85.8 %, *n* = 309/360). The Participants were randomly assigned to either the intervention group (n_{IG} = 178) or the control group (n_{CG} = 182).

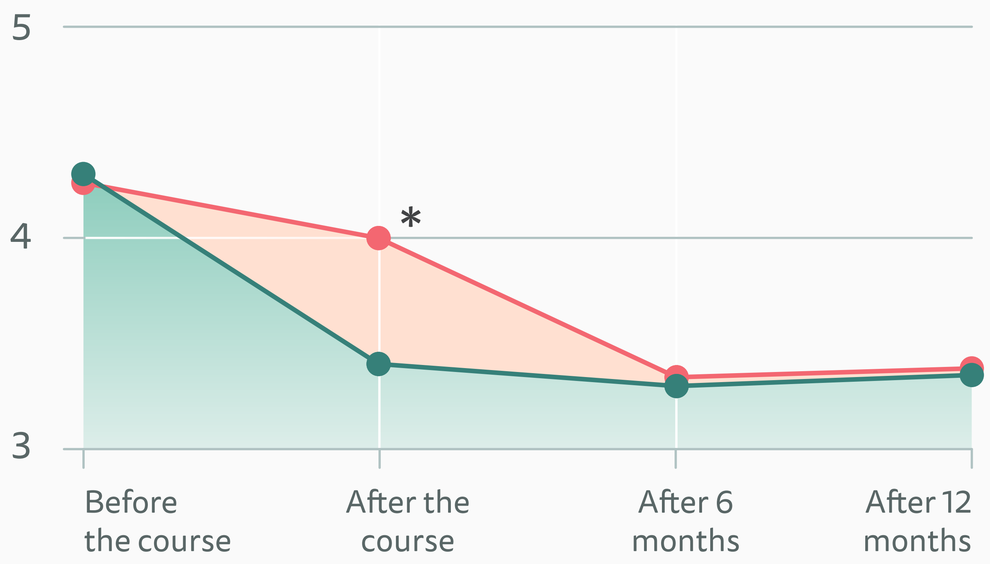
The primary endpoint of the study was pain interference, measured by the interference scale of the West Haven-Yale Multidimensional Pain Inventory (MPI) at post-measurement after 12 weeks. Secondary confirmatory endpoints included emotional functionality (Patient-Health-Questionnaire-9, PHQ-9) and health-related quality of life (Assessment of Quality of Life-8D, AQoL-8D). Further secondary endpoints were measures of pain-related health including pain intensity (Brief Pain Inventory, BPI), pain processing (Pain Processing Questionnaire, FESV), and pain acceptance (Chronic Pain Acceptance Questionnaire, CPAQ). Assessments were conducted at the start of the study (baseline) and at post-measurement (12 weeks after randomisation). Follow-up assessments of the endpoints were conducted after 6 months as well as 12 months to evaluate the long-term efficacy of the DiGA.

Regarding the primary endpoint, the intention-to-treat analysis showed a significantly lower pain interference in the intervention group at post-measurement in comparison to the control group (t = 5.95, p < .001, mean difference [*MD*] = 0.65, 95 % CI [0.44, 0.86]; d = 0.69, 95 % CI [0.46, 0.92]).

1. https://drks.de/search/en/trial/DRKS00027176

Pain interference

measured with Multidimensional Pain Inventory (MPI, interference scale, 0-6)



- HelloBetter participants
- Control group

* The control group got access to HelloBetter Chronic Pain after 12 weeks

Heber E., Etzelmueller A., Feiler M., Danzer V., Balzus L., Zimmer A., Guth M., Ebert D.D. (2023). HelloBetter ratiopharm chronischer Schmerz. Im Internet: https://drks.de/search/de/trial/DRKS00027176

A significantly larger proportion of participants in the intervention group achieved a reliable and clinically significant improvement at post-measurement in comparison to the control group (IG: 37.6 %, KG: 13.7 %, Number Needed to Treat [NNT] = 4.18, 95 % CI [3.07, 6.58]).

Regarding the secondary endpoints with confirmatory testing, a significant improvement was observed in emotional functionality (d = 0.40) as well as a significant increase in health-related quality of life (d = -0.23). Significant effects were also observed regarding various relevant measures of pain-related health (e.g., pain intensity, acceptance, and processing).

The effects of the intervention on pain interference were maintained in the IG at the follow-up assessments after 6 and 12 months. Within this group, effect sizes of d_{within} = 0.95 were observed after 6 months and d_{within} = 0.95 after 12 months.

The effects on the secondary endpoints of emotional functionality and health-related quality of life were as well maintained in the IG at the follow-up assessments. Additionally, participants of the CG, who had been given access to the intervention after 12 weeks, substantially improved as well.

Permanent Listing in the DiGA-Directory

Based on these results, the DiGA was permanently listed in the DiGA-Directory[2] of the Federal Institute for Drugs and Medical Devices (BfArM) on July 17th 2023 for the diagnoses fibromyalgia (M79.7, d = 0.81), persistent somatoform pain disorder (F45.40, d = 1.28), and chronic pain disorder with somatic and psychological factors (F45.41, d = 0.74).

These findings demonstrate that HelloBetter Chronic Pain is effective in reducing pain interference in people with chronic pain. The DiGA contributes to a substantial and sustainable improvement of the overall symptomatology of those affected by chronic pain in terms of pain-related and general health. Given the inadequate availability of psychotherapeutic services for chronic pain, effective and accessible treatment methods are of great importance. Consequently, the DiGA contributes to closing the existing care gap for people with chronic pain.

2. https://diga.bfarm.de/de/verzeichnis/01304