1. Title

„BACK-2-EFFECT“: A 2-Year Follow-up of EFFects of Exposure and Cognitive-behavioural Therapy for chronic BACK pain

2. Justification of amendment

The current study investigates the comparative effectiveness of cognitive behavioral therapy and exposure therapy in the treatment of chronic back pain and focuses on the clinically significant improvement in pain-related impairment from baseline to 6-month follow-up.
The aim of the 2-year catamnesis is to examine the sustainability of the treatment effects. For this purpose, a follow-up project was applied for and approved by the German Research Foundation (DFG). Changes and additions to the study protocol are listed below:

3. Changes in the study protocol

Following approval of a cost-neutral extension, the recruitment period was extended to 32 months and the total duration of the study to 48 months.
As part of a follow-up project, a 2-year catamnesis will also be carried out, resulting in a duration of 68 months for the main project and follow-up project (**Figure 1**).

Year	**2022**				**2023**				**2024**				**2025**				**2026**				**2027**
Quarter	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	
Main study																					
Initiation of sites																					
Recruitment																					
Intervention and follow-up																					
Database cleaning and analyses																					
Publication																					
2- Jahres FU																					
Assessments 2-year follow-up																					
Database cleaning and analyses																					
Publication																					

Figure 1: Time flow

Figure 2 shows the study design supplemented by the new survey time point. There is no change in the form of intervention or dose.

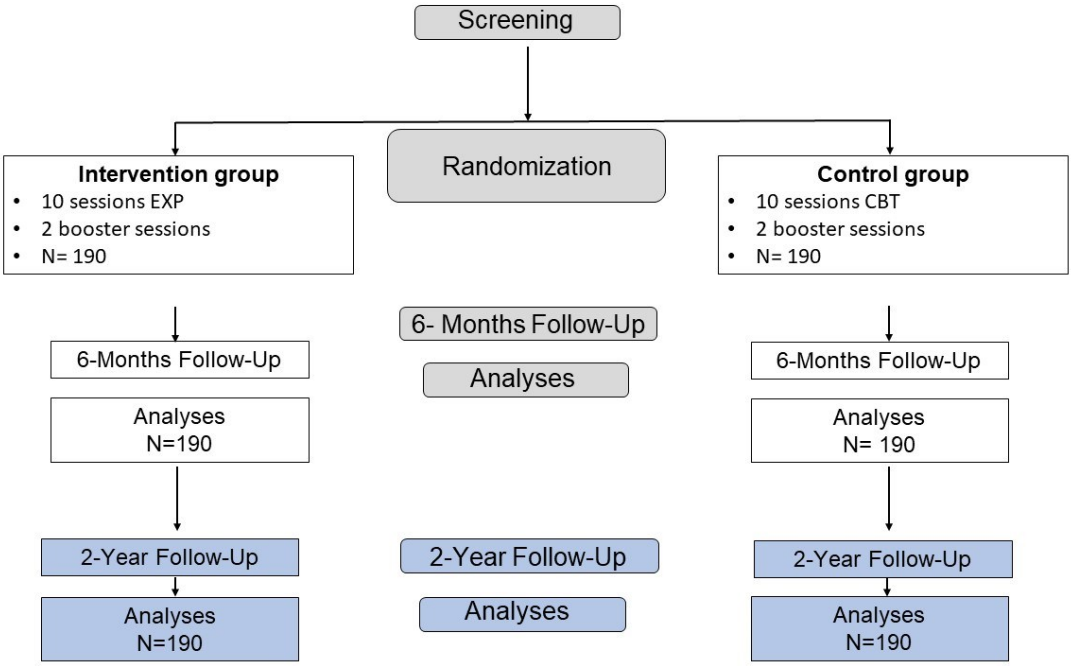

Figure 2: Study design

Data collection:

The same data will be collected as at the follow-up time T2, only two questionnaires will no longer be collected (Partnership Questionnaire-Short Version (PFB-K, (Kliem et al., 2012)) and Inventory for the Assessment of Negative Effects of Psychotherapy (INEP, (Ladwig et al., 2014)); instead, open questions on side effects will be used. A qualitative survey of the study patients on the positive and negative change processes and ideas for treatment improvements has already been developed and is running in parallel with the follow-up examinations.

Course of the study:

Assessment at visit 18 (follow-up, T2) is repeated two years after the end of the intervention (visit 14) (**Figure 3**). The study can be conducted in person on site with the study participants or online using a data protection-compliant tool (see point 5. Data protection).

Outcome and statistical analyses:

The primary and secondary outcome criteria were expanded by the (clinically significant) change from baseline to 2-year follow-up, the statistical evaluation methods were retained.

	STUDIENABSCHNITT								
	Enrolment	Randomization and Baseline T0			Intervention	Post Treatment T1	Booster sessions	Follow Up T2	2-Year-Follow Up T3
Visit	V1	V2	V3	V4	V5 - V14	V15	V16 / V17	V18	V19
Screening	X	X							
Informed consent		X							X
Inclusion and Exclusion criteria		X							
Anamnesis and Demographics				X					
Module „S“ DSF*		X						X	X
GEEE			X		X (V10)				
Randomization				X					
INTERVENTION:									
CBT					X		X		
EXP					X		X		
ASSESSMENTS: *Accompanying treatments*				X	X	X	X	X	X
*Pain medication***				X	X	X	X	X	X
QBPDS		X				X		X	X
Mini DIPS				X					
LPFS-BF and PID5BF+M		X							
PDI			X		X	X	X	X	X
*DSF****			X		X	X	X	X	X
*FESV*****			X			X		X	X
HADS			X			X		X	X
PCS			X			X		X	X
PHODA- SeV			X			X		X	X
PASS-20			X			X		X	X
BAT-BACK			X			X		X	X
PIPS			X			X		X	X
PFB-K			X			X		X	
Qualitative survey on side effects, accompanying interventions and change processes.									X
WAI-SR					X (V7, V10, V13)		X		
*REV******					X (V8-V14)				

INEP					X (V7, V10, V13)		X		
Side effects checklist					X (V7, V10, V13)		X		

Figure 3: Visit plan

* Module on the socio-legal situation, absenteeism ** including adjuvant pain medication (antidepressants)
*** adapted scales on pain intensity and experienced impairment **** Coping scale ***** only in EXP condition

4. Amendment of the study information and declaration of consent

An amendment to the existing study information and consent form was prepared, in which the extended catamnesis period, the data collected here and all aspects associated with further participation (duration, scope, objectives) are explained in detail. Study participants have indicated in the written consent for the main object whether they may be contacted again in the event of a follow-up study. If consent is given, the study participants will be contacted at the 6-month follow-up or thereafter and informed consent to participate in the 2-year catamnesis will be obtained. All information collected is subject to the applicable data protection regulations.

5. Data protection and Data security

The collection and storage of the new data is pseudonymized under the study ID assigned for Visit 2. The data protection regulations in accordance with the DSGVO will be fully complied with. The existing security measures will be expanded and adapted to the new data collection modalities (e.g. online) so that the integrity and confidentiality of the data are guaranteed at all times. An online tool with video transmission can be used to carry out the survey. For this purpose, we use the services of Arztkonsultation ak GmbH, Schusterstraße 3, 19055 Schwerin. Video transmissions via Arztkonsultation are end-to-end encrypted. This means that no one other than the participating persons can view the content of the transmission.

6. Risk and benefits

The additional examinations are associated with minimal burden for the study participants. No new measures will be collected. The extended follow-up enables a more in-depth analysis of the long-term effects, which can contribute to better scientific knowledge and potentially optimized treatment strategies.

7. Study registration

The study has been registered in the following public registry: U.S. NIH ClinicalTrials.gov

Registration number: NCT05294081. The data were supplemented by the collection of the 2-year catamnesis. The study coordinator at the lead study center is responsible for registering in the registry and maintaining the registry data.

References

Kliem, S., Job, A.-K., Kröger, C., Bodenmann, G., Stöbel-Richter, Y., Hahlweg, K., & Brähler, E. (2012). Entwicklung und Normierung einer Kurzform des Partnerschaftsfragebogens (PFB-K) an einer repräsentativen deutschen Stichprobe. *Zeitschrift für Klinische Psychologie und Psychotherapie*, *41*(2), 81–89. https://doi.org/10.1026/1616-3443/a000135

Ladwig, I., Rief, W., & Nestoriuc, Y. (2014). Welche Risiken und Nebenwirkungen hat Psychotherapie? - Entwicklung des Inventars zur Erfassung Negativer Effekte von Psychotherapie (INEP). *Verhaltenstherapie*, *24*(4), 252–263. https://doi.org/10.1159/000367928